

From the Desk of R. Lewis Dark...

THE R. LEWIS DARK REPORT

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

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Commentary & Opinion by...

R Lewis Dark
Founder & Publisher



Is Your Lab Still Making Buggy Whips?

OUR FIFTH ANNUAL *Executive War College on Lab and Pathology Management* is just around the corner. In just a few days, on May 16-17, 400 laboratory executives, administrators and pathologists will gather in New Orleans to learn the latest innovations in the management and operation of laboratories.

That makes it timely for this crusty curmudgeon to contribute his 2¢ on the immediate future for the laboratory industry. With the healthcare industry undergoing wrenching and painful change, it is becoming increasingly important for senior lab and pathology leaders to correctly identify, and act upon, the major trends reshaping laboratory medicine as we know it today.

At THE DARK REPORT, we are watching several major trends play out in the marketplace. All of them point to a positive future for laboratory medicine and pathology. Testing, whether for the purposes of diagnosis, prognosis, or patient monitoring, will become ever more essential to every nation's healthcare system.

But this coming renaissance in laboratory medicine requires new thinking by laboratory practitioners. Think of what Galileo and Copernicus had to struggle against with their "new" concepts about the Universe. Time has proved them to be more right than wrong. But during their life times, the new knowledge offered by these scientists was resisted, forcibly, by people who couldn't let go of the status quo.

Which brings me to my 2¢. Remember buggy whip manufacturers? This is the classic business school example of business thinkers who failed to adjust to the automobile. As a result, they went bankrupt. So I have a question for you—and your management team!

How many "buggy whip manufacturers" guide strategic planning at your laboratory? How many of your key management leaders are opposing the "Galileos" and "Copernicuses" in your lab, those far-sighted individuals who have the right answers *today* for your lab's strategic direction, but are pummeled mercilessly in meetings by those married to the status quo?

If my description comes uncomfortably close to the truth, then you now have the insight and recognition to change a problem before it becomes one. In the process, you will guarantee that your lab organization is one of the big winners in the laboratory marketplace of the future. **TDR**

LAB-InterLink Acquires Labotix Automation, Inc.

Omaha company makes bid to expand market for clinical lab automation hardware & software

CEO SUMMARY: Here's an interesting combination of expertise. LAB-InterLink has one of most sophisticated process control software products for running automated laboratory systems. Its acquisition of Labotix, resulting in the largest installed base of lab automation hardware in the United States, now allows it to combine proven hardware and software into a single automation solution for interested clinical laboratories.

IN A MOVE THAT'S SURE TO RILE THE market for laboratory automation products, LAB-InterLink, Inc. acquired Labotix™ Automation, Inc. of Peterborough, Canada.

The sale was made public on April 18, six weeks after the deal was closed (on March 6, 2000). Both companies are private. There was no disclosure about the sales price, and neither company publicizes its annual revenues.

With this acquisition, LAB-InterLink becomes a company to watch in the field of clinical laboratory automation. LAB-InterLink, based in Omaha, Nebraska, intends to marry its process control software products to the modular automated instruments of Labotix.

The combination of LAB-InterLink and Labotix can be expected to shake

up the existing market for lab automation products. LAB-InterLink has a different business strategy than its major competitors, who are diagnostic companies that sell testing instruments along with their automation hardware.

"We believe the combination of LAB-InterLink and Labotix positions us to become the major clinical lab automation player in North America and Europe," stated Jack Holthaus, President and CEO of LAB-InterLink. "Our interactions with lab administrators and clinical pathologists on both continents indicate that demand for clinical lab automation solutions will increase significantly beyond what has been seen during the past six years."

Holthaus thinks European labs will be faster to embrace the newer genera-

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THE DARK REPORT Intelligence Briefings for Laboratory CEOs, COOs, CFOs, and Pathologists are sent 17 times per year by The Dark Group, Inc., 1731 Woodland Terrace Center, Lake Oswego, Oregon 97034, Voice 1.800.560.6363, Fax 503.699.0969. (ISSN 1097-2919.)

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SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes THE DARK REPORT plus timely briefings and private teleconferences, is \$10.80 per week in the US, \$11.40 per week in Canada, \$12.45 per week elsewhere (billed semi-annually).

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tions of lab automation technology now entering the market. "European labs missed all the hype about TLA that caught the attention of American and Canadian laboratorians. They don't have the ingrained skepticism about TLA that is found in many North American laboratories," he observed.

"...American laboratories are now extremely careful shoppers," Holthaus explained. "They want modular automation equipment with a demonstrated track record of success..."

"That is one reason we expect European clinical labs will buy more automated systems than North American labs during the next 24 months," added Holthaus. "European relationships already developed by Labotix, based in Canada, combined with the LAB-InterLink products, will make us a tough competitor overseas.

"The United States presents a different type of opportunity," he continued. "During the 1994-1999 period, there was a real disconnect between the promise of TLA to deliver significant economic benefits, and its actual performance in the pioneering labs which installed TLA equipment.

"As a result, American laboratories are now extremely careful shoppers," Holthaus explained. "They want modular automation equipment with a demonstrated track record of success and they want the vendor to stand behind the performance of its products.

"That plays to the strengths of the post-acquisition LAB-InterLink," noted Holthaus. "With an installed base of 22 laboratories in North America, we have far more satisfied customers than any other lab automation competitor.

"We intend to leverage this installed base of satisfied users," he continued. "Marrying the Labotix automation hardware with the LAB-InterLink process control software creates an integrated clinical lab automation system that will be highly competitive in the marketplace.

"Also, we do not believe total laboratory automation is the right solution for the majority of clinical laboratories," noted Holthaus. "Our products are engineered to automate discrete steps in the testing process.

"This is a modular approach. Clinical labs can identify specific places within their operation where mechanization and automation can improve productivity, lower costs, and boost quality," he said. "Labs can achieve this on a much smaller capital investment than TLA. Furthermore, it gives the lab flexibility in downstream years to automate additional steps, yet always with a capital investment that generates a reasonable ROI (return on investment)."

Strong Competitor

Another reason why THE DARK REPORT believes that LAB-InterLink will be a strong competitor in the lab automation marketplace is its capabilities in process control software. (See sidebar on page 4). Rodney Markin, M.D., Ph.D. is the founder and Chairman of LAB-InterLink. He recognized the importance of process control software as he studied the performance of the first generation of TLA installations during the mid-1990s.

To boost LAB-InterLink's capabilities in process control software, he recruited Jack Holthaus to be President and CEO in 1998. Perceptive clients of THE DARK REPORT will recall that Jack Holthaus was the founder and President of **Advanced Laboratory Group** (ALG), based in Eugene, Oregon.

Process Control Software Provides the Brain To Drive Lab Automation and Mechanization

ONE ASPECT THAT DIFFERENTIATES LAB-InterLink from other clinical laboratory automation equipment vendors is the priority it gives to process control software.

"Process control software is essential to the success of any clinical laboratory automation," observed Jack Holthaus, President and CEO of LAB-InterLink. "It's the brain that does the thinking for the automated processes.

"When equipment is installed to move specimens through the laboratory and transport them to different instruments and processing workstations, it needs guidance," he continued. "In the non-automated lab, laboratorians make the decisions about what to do with individual specimens at each step in the process. But when the lab is automated, software must perform this function. For automated systems to function properly in the clinical lab, it must be directed by

This company developed and sold laboratory information system (LIS) software. It was acquired by **HBOC & Co.** (now **McKesson/HBOC**) in 1995. By the mid-1990s, Holthaus recognized the importance of process control software to the success of LIS products and automation hardware systems. (*See "New Features Slated for Laboratory Information Systems," TDR, March 31, 1997.*)

Since his arrival at LAB-InterLink in 1998, Holthaus has spearheaded the development of sophisticated process control software. The goal was to incorporate the rules of clinical laboratory medicine into the process control software. This would allow the software to direct specimens through the mechanized and automated lab systems

rules-based process control software. These rules are built upon clinical laboratory science."

"When process control software is capable of making the decisions that formerly would be made by the laboratorian, then some outstanding benefits begin to accrue," added Holthaus. "For example, there is a widely-used chemistry instrument that can generate up to 5,300 different error messages. Each requires a response by the operator.

"When process control software can respond to these error messages, it requires much less labor to operate its instruments. Typically, as few as two med techs can efficiently operate as many as 10 or 12 large instruments per day. The challenge is developing process control software that incorporates the vast knowledge and experience that is used by laboratorians."

using the same knowledge and thinking as laboratorians.

If it was shrewd of Dr. Markin and the LAB-InterLink executive team to recognize the importance of process control software and invest in developing that automation tool, then it was an equally shrewd decision to acquire Labotix.

"This is an interesting marriage," stated Holthaus. "Each company approached the problems of clinical laboratory automation from a different direction. Labotix was focused on hardware solutions while LAB-InterLink emphasized software solutions.

"For that reason, we believe combining our software package and equipment with Labotix's hardware creates a complete solution for those clinical laboratories now ready to

automate specific areas of their testing activities," noted Holthaus.

"Most clinical labs would gain significant benefit from the mechanization and automation of specific work steps," he explained. "This is component-based automation. Many Lab-InterLink customers report economic paybacks of between six and 24 months from their automation projects. We believe the fuller integration of their hardware with our process control software will further improve the performance of this equipment."

Installed in 22 Laboratories

Holthaus' confidence may be well-founded. The post-merger Lab-Interlink has 22 labs now using its automation solutions. That significant share of the clinical lab automation market is not a coincidence. Labs using the company's products report favorably about its performance.

Thus, the acquisition of Labotix by LAB-InterLink is a signal that the market for clinical lab automation is about to shift into a new phase. The number of new TLA installations will probably not increase over that of recent years.

Instead, THE DARK REPORT predicts that clinical laboratories will increasingly opt for workstation automation (where related instruments are connected) and modular automation (where discrete steps in specimen handling and transport are automated).

Several Reasons

There are several reasons why this will be true. First, TLA requires a huge capital investment, much more than workstation and modular automation.

Second, existing TLA technology locks the laboratory into a rigid operational configuration. Once it is installed, it is expensive to alter it to incorporate new diagnostic instruments and other technology innovations. In comparison, workstation and modular

automation solve immediate operational problems for the lab, but retain flexibility to incorporate new technology as it appears in the future.

Third, the return on investment (ROI) for workstation and modular automation can be surprisingly short. Site visits to labs which installed such solutions reveal paybacks of six months to one year are attainable—along with substantial improvement in how specimens are tracked and handled.

Fourth, the ease of implementation makes it more attractive to hospital CEOs. Most workstation and modular automation can be installed and made operational with a minimum of disruption to the existing laboratory operations.

Given these benefits, THE DARK REPORT predicts that TLA will languish relative to workstation and modular automation during the next few years. What makes LAB-InterLink the most interesting automation vendor to watch during this period is its commitment to process control software.

Information Age

If the Internet is the herald of the information age, then hardware vendors which incorporate information and knowledge management capabilities into their products will have the edge over those who don't. That is why LAB-InterLink's head start in laboratory process control software makes it the company to watch in the field of clinical laboratory automation.

TDR

Contact Jack Holthaus at 402-595-3767.

Jack Holthaus Will Speak at the EXECUTIVE WAR COLLEGE

Jack Holthaus will appear at the *Executive War College's LAB CEO SUMMIT*, scheduled for Thursday, May 18 at the Fairmont Hotel, New Orleans. Lab CEOs and Administrators can call 800-560-6363 for information and to receive an invitation to this special event.

New Automation Tools Ready for Clinical Labs

These new tools require lab administrators to utilize more rigorous business methods

CEO SUMMARY: Evidence grows that workstation automation and modular automation can be cost-effective solutions in the clinical laboratory. But the newest generation of automation technology presents lab administrators with a new challenge. Financial analysis and workplace reengineering are now essential skills for success. Lab managers who fail to upgrade their capabilities will find themselves at a disadvantage.

SEVERAL TRENDS IN HEALTHCARE will soon converge and create a new set of challenges for hospital laboratory directors.

This convergence will require successful hospital laboratory administrators and clinical pathologists to become more proficient at three skills: 1) workflow reengineering; 2) productivity and financial analysis; and 3) ability to effectively implement change in the clinical laboratory.

These skills will complement the experience in clinical medicine needed to manage a laboratory. But the successful hospital lab manager will learn to use business management skills in concert with scientific knowledge to effect continuous operational change in the lab organization.

Three Basic Trends

THE DARK REPORT identifies three basic trends about to converge and cause this change. First, ongoing improvements to laboratory automation technology and point-of-care testing will make it feasible, even mandat-

tory, to reconfigure hospital core laboratories in new ways. These technologies will make it possible to perform testing faster, more accurately, and at lower cost.

Second, hospital CEOs and senior administrators are increasingly frustrated with the inertia and inability of many lab directors and clinical pathologists to "get with the program" and continuously improve lab operations. To combat this inertia, hospital CEOs are retaining outside experts to bring change to their laboratories.

Three, the evolving American healthcare system now requires providers to be skilled at assessing the economic benefits of new technologies and services and competent at introducing them into clinical use. This means that skills in financial analysis and management implementation will be just as important as skills in medicine and science.

These trends were identified by THE DARK REPORT in earlier intelligence briefings for its clients. The

recent interview with **LAB-Inter-Link, Inc.**'s President and CEO, Jack Holthaus, brings further evidence that these trends are exerting greater influence. (*See pages 2-5.*)

"Recently several statistically-valid surveys of hospital system CEOs were conducted," said Holthaus during his exclusive interview with THE DARK REPORT. "The goal of the survey sponsors was to learn what these CEOs thought about their hospital laboratory management."

Willingness To Outsource

In this survey, hospital system CEOs were asked about their willingness to outsource hospital laboratory services. One surprising conclusion of this survey was that remarkably high numbers of CEOs are dissatisfied with the existing management of their clinical laboratory organization.

The survey concluded that one reason for this dissatisfaction was not unhappiness about the quality of lab testing, but rather the lack of initiative by lab directors to speedily adopt improvements to the lab's cost structure and capabilities.

The results of this survey must be considered in tandem with another phenomenon. "It is common knowledge among diagnostic vendors and commercial laboratory companies that the number of senior hospital system administrators willing to discuss joint laboratory ventures is on the rise," noted Holthaus. "Add these two developments together, and it's obvious to see that a period of significant change to hospital laboratory organizations is about to commence."

Hospital CEOs Dissatisfied

The observation by Holthaus about these two healthcare trends complements observations made by THE DARK REPORT. One conclusion from the survey of hospital system CEOs is

New Automation Tools Provide Opportunity

One major difference between the lab automation tools hitting the marketplace today, and the TLA (total lab automation) systems of the mid-1990s is their flexibility and relatively lower cost.

Workstation automation and modular automation address the needs to mechanize and automate rote steps in the laboratory testing process. For example, at **ARUP Laboratories** in Salt Lake City, Utah, the decision was made to automate the accessioning process first.

This would solve a major operational roadblock at ARUP and facilitate additional automation in subsequent years. Charles D. Hawker, Ph.D., who directs ARUP's automation efforts, will be at the upcoming *Executive War College* in New Orleans on May 16-17 to discuss this project and report on its performance.

that their dissatisfaction with laboratory directors stems from the lack of professional management skills. It validates the findings done by **Premier, Inc.** in 1998, when they studied the reasons why hospital laboratories took years to pursue obvious cost-saving opportunities that commercial labs had rapidly adopted, such as consolidation and regionalization. (*See TDR, June 15, 1998 and July 6, 1998.*)

Holthaus had an opinion on why this situation exists. "Hospital system CEOs are consistently driven by the equation between economic cost and clinical benefit," he observed. "From their perspective, a proposition to consolidate lab testing, or acquire automation technology, is basically a business and financial decision. It is not clinical.

"These hospital CEOs want their ancillary services administrators to be both ready and willing to make tough decisions," he added. "Yet lab medicine has always been slow to change."

"For example, it is common for us to meet with lab managers who proudly tell us 'We cut lots of cost and people from our lab. We are lean and mean,'" continued Holthaus.

"They may have 16 people per day handling eight to ten large instruments," he continued. "We demonstrate to them how, by installing our automation solutions, two people at one control point can do the same work. After studying how our automation solution makes that attainable, they hesitate to commit. For them, it seems safer to keep the status quo."

Holthaus' example has a familiar ring. There is a stereotype that hospital lab managers are "reluctant to change and would prefer to keep the status quo in their lab." Most clinical laboratorians agree on the validity of this lab industry stereotype.

The results of the recent hospital system CEO survey offers evidence that hospital CEOs are increasingly dissatisfied with lab administrators who fit this stereotype. CEOs are demonstrating, by their willingness to discuss outsourcing laboratory functions, that they are ready to correct this unacceptable situation.

The laboratorians to be hardest hit when these healthcare trends finally converge will be those hospital lab directors who fail to heed the warning signs.

THE DARK REPORT offered examples of this in our last issue. The emerging trend of shared laboratory service organizations, organized between hospital systems, certainly is proof. **Spectrum Laboratory Network** in Greensboro, North Carolina was organized by three different hospital systems. **Carolina Laboratory Network** in Charlotte, North Carolina is another example.

The recent announcement that **Aurora Health Systems** of Milwaukee would pool its laboratory services with those of **Advocate Health Care** in Chicago followed on the heels of news that CEOs at Chicago's **Rush-Presbyterian-St Luke's Medical Center, University of Illinois at Chicago Medical Center, and Cook County Hospital** are launching discussions to start a shared laboratory organization.

Obvious Conclusion

All of these marketplace developments point to an obvious conclusion: hospital lab managers who consciously attempt to preserve the status quo will increasingly be seen as a problem.

Their hospital CEO generally does one of several things to resolve the situation: 1) replace the laboratory manager; 2) outsource the laboratory or bring in outside experts to implement changes in the lab; 3) joint venture with a commercial lab company; or 4) enter a shared laboratory services arrangement with other hospital systems and put the lab under the direction of someone with experience in business and financial management.

In general, clients and regular readers of THE DARK REPORT already recognize these changes and are striving to proactively bring positive change into their laboratory. Their initiative is a big reason why they will survive this next cycle of lab industry evolution.

The laboratorians to be hardest hit when these healthcare trends finally converge will be those hospital lab directors who fail to heed the warning signs. Hospital CEOs, finally impatient at the lack of progress in the laboratory, will take direct action to place their laboratory in the hands of individuals who will change the lab. **TDR**
Contact Jack Holthaus at 402-595-3767.

THE DARK REPORT's 1999 LIS SALES RANKINGS

LIS Vendors Moving to Internet

SALES OF LIS SYSTEMS SLOWED DURING 1999 due to concerns about Y2K problems. But the real story in the LIS arena was the impending arrival of technology that takes advantage of the Internet and the Web.

Sales champs in THE DARK REPORT's annual ranking of the *Top Ten LIS Vendors* for 1999 are **Meditech** and **Fletcher Flora**, in the categories of LIS sales to hospitals and non-hospitals respectively. In the category of new sales of LIS to hospitals, Meditech placed 100 systems in 1999. Second were Fletcher Flora and **McKessonHBOC**, each placing 87 and 78 systems, respectively.

Sales in the non-hospital category are primarily to independent clinical laboratories. First was Fletcher Flora's 130 systems, followed by **Schuylar House** (66 systems), and **Lab Soft** (43 systems).

TOP TEN LIS VENDORS RANKED BY:

Hospital Sales (1999)		Hospital Installations (1999)					
Rank	Company	New Sales 1999	Cumulative Per Cent	Rank	Company	New Sales 1999	Cumulative Per Cent
1	Meditech	1,132	21.3%	1	Meditech	1,132	21.3%
2	Fletcher Flora	87	28.1%	2	Sunquest	981	39.8%
2	McKessonHBOC	78	40.4%	3	Cerner Corp	675	52.5%
4	Sunquest	65	50.7%	4	McKessonHBOC	479	61.5%
5	Cerner Corp	54	59.2%	5	Creative Computer Apps	223	65.7%
6	Creative Computer Apps	28	63.6%	6	SCC Clinical Info Sys	218	69.8%
7	Schuylar House	25	67.5%	7	Isys/Biovation	200	73.6%
8	SCC Clinical Info Sys	23	71.1%	8	Fletcher Flora	188	77.1%
9	Citation	19	74.1%	9	SMS	180	80.5%
10	Lab Soft	18	76.9%	10	CPSI	167	83.5%
Total Top Ten Vendors		497	76.9%	Total Top Ten Vendors		4,443	83.5%
<i>Total All Vendors</i> (Total new sales in 1998: 735)		634	100.00%	<i>Total All Vendors</i> (Total installations in 1998: 5,410)		5,317	100.00%

Provided by: R.L. Johnson & Associates

In total installed systems, Meditech dominates the hospital category. It has 1,132 LIS systems, representing more than 20% of the nation's hospitals. **Sunquest** and **Cerner** followed with 981 and 675, respectively. Among non-hospital systems, it is Fletcher Flora, Schuyler House, and **Hex Information Systems** with 282, 216, and 121, respectively.

The number of non-hospital installations declined from 2,231 in 1998 to 1,699 in 1999. This demonstrates that consolidation and financial woes continue to shrink the number of independent laboratory organizations in the United States.

The declining number of LIS vendors is reflected in the 1999 numbers. That trend may continue as new information management technology continues to roil the healthcare marketplace.

This new information technology is

hitting hospitals and clinical laboratories at an ever-accelerating pace. "Right now, the two hot trends in laboratory information systems are ASP and wireless personal digital assistants (PDA) that use browsers to access to lab results and order tests," declared Bruce A. Friedman, M.D., Director of Ancillary Information Systems and Professor of Pathology at the **University of Michigan Medical Center** (UMMC). "ASP stands for application service provider. This is a software business model where the software vendor maintains the software on its own server and 'rents' the applications to its hospital customers who access them remotely.

"Basically, these technologies don't require any infrastructure, such as a local large host computer or a computer network. They will allow laboratories to leapfrog the existing technology base," he

added. "Here's an example. After speaking at an AACC meeting recently, a laboratorian from Argentina approached me. She helped develop a network of laboratories in Argentina that would like to derive benefit from this association.

"The ASP solution in this geographic context could potentially mean that the LIS/ASP vendor can install a single server to host all of the labs in Argentina. Then only a Web browser-equipped PC would be needed for any lab in the organizational network to access the master LIS software and become fully integrated.

"Wireless, hand-held devices are hitting the market just as quickly as ASP," continued Dr. Friedman. "Right now, **Detroit Medical Center** (DMC) is prototyping the introduction of Palm computers. DMC's information system vendor is exclusively Cerner. DMC's first use of the palm units

TOP TEN LIS VENDORS RANKED BY:

Non-Hospital Sales (1999)		Non-Hospital Installations (1999)					
Rank	Company	New Sales 1999	Cumulative Per Cent	Rank	Company	New Sales 1999	Cumulative Per Cent
1	Fletcher Flora	130	38.5%	1	Fletcher Flora	282	16.6%
2	Schuylar House	66	58.0%	2	Schuylar House	216	29.3%
2	Lab Soft	43	70.7%	3	Hex Lab. Consulting	121	36.4%
4	Creative Computer Apps	12	74.3%	4	Creative Comp Apps	104	42.5%
5	Sunquest	11	77.6%	5	Isys/Biovation	101	48.4%
6	Psyche Systems	8	80.0%	6	Sunquest	87	53.5%
7	SCC Clinical Info Systems	6	81.8%	7	New Lab Force	50	56.4%
7	Intellidata	6	83.6%	8	SCC Clinical Info Systems	45	59.0%
9	Hex Information Systems	3	84.5%	9	Pysche Systems	45	61.7%
9	Cerner	3	85.3%	10	Dynamic Healthcare	34	63.8%
Total Top Ten Vendors		288	85.3%	Total Top Ten Vendors		1,085	63.8%
<i>Total All Vendors</i> (Total new sales in 1998: 303)		338	100.0%	<i>Total All Vendors</i> (Total installations in 1998: 2,231)		1,699	100.00%

Provided by: R.L. Johnson & Associates

will be read-only, allowing the physician to download clinical data into his palm from any location within range of the wireless network.

"Another exciting application of this new information system technology is happening at Sunquest," noted Dr. Friedman. "Their Clinical Event Manager (CEM) has a device that sits atop the computer hub.

Doctors Customize Rules

"CEM has rules that can be designed and modified by the physician-customers themselves," he continued. "If a doctor wants only his stat results, and wants them at a certain clinic location on Wednesdays, CEM will push these results to him at that site via email, alpha pager, Palm PDAs with pager, or printer. Sunquest has already installed this CEM feature in nine sites. It has contracts to proceed for another nine."

Dr. Friedman is probably the nation's most knowledgeable expert on laboratory information system technology. He believes the Web-enabled age will hit the laboratory industry at light speed. "The low cost to implement and use a web-enabled lab information system will be the incentive that causes laboratories to rapidly switch to this technology," predicted Dr. Friedman.

ASP Revenues To Boom

"In fact, the CEO of one major LIS company told me recently that, by 2002, 50% of his company's sales will come from ASP services, not the traditional fat client model that we know today," added Dr. Friedman. "This is a good indication of how swiftly this technology changeover will occur."

Dr. Friedman is bringing innovations to his clinical laboratory. "Right now, we are working on a pilot project. We want to implement an application known as 'web clipping,'" he said.

"At UMMC, we are installing 3-Com software on top of our Cerner

database. This software will simply reformat existing lab data and download it to Palm VII wireless devices carried by our doctors. It takes our existing laboratory test results data and allows it to be accessed, on demand, by wireless units. We expect this feature to be running as a prototype in the next 60 days."

THE DARK REPORT believes the laboratory industry is already in the early stages of an information management revolution. This revolution will run concurrent with the coming explosion in genomics-based assays and the ongoing miniaturization of test instruments.

For this reason, it is imperative that every clinical laboratory and pathology group practice immediately develop a business strategy for the Internet. All labs should seize this once-in-a-lifetime opportunity to be first to enhance the services they offer physicians, patients, and payers. Such proactive efforts can reward the enterprising lab organization with competitive advantage, increased market share, and greater profits. **TDR**
Contact Bruce A. Friedman, M.D. at 734-764-8333 or bfriedma@umich.edu.

• SPECIAL WEB-INFO DAY •

TO STAY AHEAD OF THE LAB INFORMATION management revolution, THE DARK REPORT invited some of the nation's leading innovators in lab information services to come to the *Executive War College* and discuss their current products and business strategies.

Thursday, May 18 will be the first-ever national lab gathering devoted exclusively to Web-based lab information technology. Dr. Friedman will discuss the technology, and moderate presentations by a panel of vendors that includes **Advanced Health Technologies, Abaton, Cerner, Health-eon/ WebMD, Sunquest/Antrim, and Specialty Laboratories.**

To register or for information, call

800-560-6363

Luminex Raises \$83 Mil In Public Stock Offering

Multiplex testing technology finds ready acceptance with diagnostics & drug firms

CEO SUMMARY: During the past year, Luminex Corporation moved swiftly to push its LabMAP™ multiplex testing technology into the bioassay marketplace. It found high interest among companies in the pharmaceutical, diagnostics, and bioresearch industries. Luminex executives say that a number of companies are working to have FDA-approved diagnostic test kits available for laboratories by year's end.

ARMED WITH A WAR CHEST OF \$82.8 million from its recent IPO (initial public offering), **Luminex Corporation** is ready to further push its LabMAP™ multiplex testing technology into the bioassay marketplace.

Luminex, based in Austin, Texas, developed a patented technology that incorporates microscopic plastic beads, small lasers, digital signal processors, and proprietary software to perform up to 100 individual assays on a single drop of fluid.

Multiplexed Test Platform

THE DARK REPORT predicts that Luminex's LabMAP testing system will significantly change the way clinical laboratories perform diagnostic testing. The clinical laboratory world was first introduced to Luminex in THE DARK REPORT intelligence briefing of December 21, 1998.

When Luminex President and CEO Mark Chandler, Ph.D., appeared at last year's *Executive War College* and the private Lab CEO SUMMIT which fol-

lowed, lab executives and pathologists were quick to recognize the transformational potential of the LabMAP system.

"As of March 31, 2000, we've sold 128 LabMAP systems," stated Randy Marfin, Vice President of Business Development. "About one-third of these systems were purchased by clinical laboratories and diagnostic companies."

Several of the nation's largest laboratories and diagnostics companies were first to acquire the LabMap system. Among them are **Abbott Laboratories**, **Bio-Rad Laboratories**, **Laboratory Corporation of America**, **Mayo Clinic**, **National Institutes for Health**, and **Quest Diagnostics Incorporated**.

Within the field of clinical laboratory testing, these companies are developing Luminex technology for two applications. "Diagnostic companies are developing test kits for use on LabMAP," said Dr. Chandler. "We've licensed our technology to a number of companies. Their progress indicates that FDA-approved test kits may be available by the end of this year."

Clinical laboratories are exploring ways to internalize existing tests onto the LapMap platform under "home brew" guidelines. Their objective is to reduce the cost of using existing methodology on specific assays while improving the quality of results.

Daily Commercial Lab Use

"We believe several of these laboratories have completed their correlation studies," indicated Marfin. "At least some of these customers will soon be using LabMAP systems for daily test production in their laboratory."

According to Marfin, early applications will be in genetic testing and serology. "Labs want to use LabMAP for things like Factor 5 Leiden, paternity testing, and autoimmune procedures which require multiple tests on a single specimen."

The LabMAP system is built around three robust technologies that have existed for quite some time. Luminex figured a way to combine them into a paradigm-shifting bioassay testing platform.

Dyed Microsphere Beads

First, the LabMAP system uses standard plastic microsphere beads that function as sites for covalent ligand attachment. These microspheres have been used in many different types of diagnostic tests for several years. Luminex has a patented method for dyeing the microspheres. Each bead set has a different color and carries a different bioassay.

Once the beads are introduced into a specimen, which can be as small as 10 microliters, up to 100 discrete assays can be performed simultaneously on that specimen. The beads pass through a pair of laser beams (the second robust technology), resulting in fluorescent emissions that instantly identifies each bead and measures the reaction.

Luminex's Technology Attracts Investor Interest

When Luminex Corporation brought its IPO (initial public offering) to market last month, there was strong financial support by the investment community.

Luminex raised \$82.6 million from the IPO, which was fully subscribed. Shares were issued at \$17.00, and the price climbed immediately. At press time, Luminex stock currently trades in the range of \$21.00 per share. With 26.7 million shares outstanding, this gives Luminex a market capitalization of \$560 million.

Annual revenues at Luminex were only \$2.6 million during 1999. Its market capitalization of half a billion dollars demonstrates that the investment community has high expectations for Luminex.

Although diagnostics testing is not the biggest potential market for Luminex technology, it is expected that diagnostic applications will be first to demonstrate commercial viability. FDA-approved test kits may be ready for the market as early as year's end.

The third robust technology is Luminex's patented DSP (digital signal processor) software, which accumulates the data and processes it into clinically accurate results.

Typically, the LabMAP system can multiplex a 100-assay lab specimen in as little as three seconds. The retail price for a LabMAP system is \$25,000. For an additional \$7,000, the instrument can be interfaced to an autoloader, such as the Zymark Twister.

Open Technology Platform

"Luminex's business strategy is to offer the LabMAP system as an open technology platform," explained Chandler. "**Intel** and **Microsoft** offer their computer chips and operating software as an open technology. They allow any company to buy or license these technologies for specific uses.

Similarly, our LabMAP system is designed to be an open technology platform that any company can license and use for bioassay applications."

Within the clinical laboratory industry, the Luminex LabMAP system is gaining credibility. The instrument is compact, easy to operate, durable, and can be installed in an automated setting. Its modest purchase price means that it is suitable for use outside the core lab, such as in emergency rooms and physician office labs.

It will take additional time before clinical pathologists and laboratorians grasp the full potential of the LabMAP system

What is most intriguing is LabMAP's capability of multiplexing 100 different tests on a specimen of only 10 microliters, at a relatively low cost. This combination of low cost, ease of use, and multiple analytes will allow diagnostic vendors to develop unimagined combinations of tests that can be performed, in seconds, in a variety of healthcare settings outside the core laboratory.

To that end, Luminex has an agreement with Bio-Rad to develop and distribute test kits. Luminex is also collaborating with Abbott Laboratories to evaluate LabMAP's effectiveness with Abbott's "next generation" PSA (prostate specific antigen) tests.

Luminex is even cooperating on a project to develop a point-of-care version of LabMAP. In particular, the goal is to design an instrument capable of functioning in an ambulance or non-laboratory environment. THE DARK REPORT speculates that the military would have a high interest in funding the development of a LabMAP system

that would operate dependably in battlefield settings. Once available, such a version could find ready applications in the civilian marketplace.

"These are exciting times for us," said Marfin. "We have signed 17 deals with pharmaceutical, bioresearch, and diagnostic companies, with many more in the pipeline. Diverse applications are therefore being developed very quickly.

Wide Spectrum Of Assays

"We anticipate that, as our strategic partners bring test kits to the clinical laboratory market, there will be a broad spectrum of assays, particularly involving nucleic acids detection and immunoassays," he added.

THE DARK REPORT observes that the Luminex LabMAP technology is one of these paradigm-shifting developments which was unanticipated by experts in laboratory medicine. The reason is simple. Its technology is rooted in other scientific disciplines.

For this reason, it will take additional time before clinical pathologists and laboratorians grasp the full potential of the LabMAP system to improve the cost-benefit equation of laboratory medicine.

Hospital CEOs Dissatisfied

Meanwhile, several of the nation's largest laboratory companies are ready to put LabMAP into daily commercial use. If LabMAP delivers the cost savings predicted by its developers for "home brew" assays, these labs may gain an economic advantage over labs continuing to use traditional methods.

Luminex's LabMAP provides yet another example that new technology will provide laboratories with the tools needed to improve their financial fortunes while offering enhanced lab services to physicians and patients. **TDR**
Contact Mark Chandler and/or Randy Marfin at 512-219-8020.

Lab Industry Briefs

QUANTUM DOT CORP. TO COLLABORATE WITH GENENTECH

PROGRESS IS SWIFT AT **Quantum Dot Corporation**, based in Palo Alto, California. Quantum Dot announced an agreement to collaborate with **Genentech, Inc.**, headquartered in San Francisco, California. The goal is to evaluate Qdot™ nanocrystals in a number of Genentech's biological research assays.

Quantum Dot also raised another \$30 million in private venture capital last month. Qdot nanocrystals are nanometer-sized semiconductor crystals which light up like molecular-sized LEDs and can be used like fluorescent markers in bioassays. (*See TDR, February 14, 2000.*)

Qdot nanocrystals can be used to create multiplexed bioassays. Quantum Dot Corporation has its eye on the diagnostics marketplace. "We've already signed a deal with one of the five largest diagnostics companies," said Sang-ita Parikh, Marketing Manager at Quantum Dot. "We expect to complete one more partnership agreement involving diagnostics by year's end."

Qdot nanocrystals are an emerging technology that can be used to create multiplexed bioassays which have increased accuracy and lower cost. Quantum Dot Corporation wants to develop its technology through partnerships with selected companies.

HEALTHEON/WEBMD LOSES SOME LUSTER WITH WALL STREET

AFTER A BLISTERING YEAR OF BIG acquisitions and lots of publicity, **Healtheon/WebMD**'s first quarter

earnings proved disappointing to investors. Although revenue increased from \$17.6 million to \$65.9 million over the same quarter last year, Healtheon/WebMD's net loss soared.

The company lost \$431 million in the first quarter, compared to only \$18.6 million for Q1 in 1999. On the positive side, there was steady growth in key services offered by the health-care E-commerce firm.

Healtheon/WebMD says that 100,000 physicians are now registered users of WebMD Practice. This is a 47% jump from the 68,000 registered physician users in fourth quarter of 1999. It said transactions were 131 million for first quarter, of which 4.8 million were Internet transactions.

Healtheon/WebMD is working to install its Web browser-based laboratory test ordering/reporting product in several laboratories. **Laboratory Corporation of America**, **DIANON Systems**, and **UroCor** have contracted to use the Healtheon/WebMD lab solution.

TELEPATHOLOGY MOVES AHEAD WITH ILLUMEA

ONE COMPANY THAT'S ATTRACTING plenty of attention from the pathology profession is **Illumea Corporation**, based in Newport Beach, California.

Illumea's telepathology system will be used by **DIANON Systems, Inc.** to link its headquarters laboratory in Stratford, Connecticut with the DIANON laboratory in Tampa Bay, Florida. It will be used for intracompany teleconsultations. Illumea was also recently selected as a preferred vendor by **Pathology Service Associates**, headquartered in Florence, South Carolina.

LabCorp Buys Two More California Laboratories

Company demonstrates its commitment to nation's largest lab testing marketplace

CEO SUMMARY: *Laboratory Corporation of America is serving notice that it intends to increase its competitive presence in California, the largest market for diagnostic testing in the United States. It recently signed agreements to purchase two respected independent laboratory companies, one in Los Angeles, the other in San Diego. Owners of both acquired companies had different motives for selling.*

CALIFORNIA'S STATUS as a bellwether state for the laboratory industry was affirmed again with the news that **Laboratory Corporation of America** would acquire two independent labs in Southern California.

On April 19, 2000, LabCorp completed the purchase of **Bio-Diagnostics Laboratories** (BDL) of Torrance, California. Just 12 days later, LabCorp signed an agreement to purchase **Pathologists Medical Laboratories** (PML) of La Jolla, California. The sale is expected to close around June 1, 2000.

Both labs were founded early in the 1980s. BDL had annual revenues of \$12 million, while PML is estimated to have a similar amount of business from physician office testing.

"BDL just completed its best financial year ever," stated Al Lui, M.D., President and CEO of BDL. "For the past couple of years, the competitive market in California was quiet. The big labs, like **Unilab**, LabCorp, **SmithKline Beecham**, and **Quest** were all distracted by internal priorities.

"As a result, independent laboratories like ours had the opportunity to perform the things we do best, without the pressure of deep discounting in the California marketplace to retain existing accounts," noted Dr. Lui.

Decision To Sell BDL

"We decided to sell BDL at this time because we want to concentrate on our core competency, which is pathology," he continued. "In Southern California, the new marketing efforts of pathology companies like **DIANON**, **UroCor**, and **USLabs** caught our attention. The sale of BDL allows us to reallocate our strategic resources and management priorities exclusively on pathology services."

One interesting aspect to the BDL/LabCorp relationship is the fact that Dr. Lui's pathology group, **Affiliated Pathologists Medical Group** (APMG), began providing pathology services to LabCorp in Southern California last September. "It was this ongoing interaction with LabCorp that gave us the trust factor to

proceed with the sale," noted Dr. Lui. "We became impressed with its renewed commitment to both the California market and to higher levels of customer service."

Different Story At PML

At PML, the story was slightly different. During 1999, the long-standing joint venture between PML and **Scripps Healthcare** was dissolved. PML had built a tightly-integrated laboratory organization to serve the hospital lab testing needs of Scripps along with PML's physician office business.

"We've had an excellent business throughout San Diego County," observed Phillips I. Gausewitz, President and CEO of PML. "In considering our strategic options after the dissolution of the JV, we wanted to build upon the business franchise we had developed with the local healthcare community. We decided the best thing for our customers and employees was to align ourselves with a lab company that had both the money and the motivation to expand our business."

PML's business achievements were recognized when it became the only lab in 1999 to receive the Betty Martin Innovative Leadership Award from the **Clinical Laboratory Management Association** (CLMA).

Highly-Valued Assets

At LabCorp, the business reputation of both acquired labs is an important asset. "These are well-known, respected labs," said Al Troub, Senior Vice President and Divisional Manager at LabCorp. "BDL and PML provide us with an important foundation for additional growth in California."

LabCorp also has keen interest in the caliber of the people it is gaining from BDL and PML. "The quality of the people is just as important as the core business," declared Troub. "We are retaining large numbers of these

Customer Satisfaction Is Now A Prime Goal

"We've learned something very interesting from our customer satisfaction surveys," stated Pam Sherry, Vice President of Investor Relations at LabCorp. "High levels of customer satisfaction translate directly into increased profits."

"Under Chairman Thomas MacMahon's leadership, LabCorp is working to build service levels and the satisfaction of our lab customers," she continued. "As a result, we regularly monitor both our service performance and the satisfaction of our clients. It allows us to measure and correlate how changes in service lead to similar changes in profitability. With our California acquisitions, we will be using these surveys to help us maintain the tradition of good service that BDL and PML have established over the years."

people at all levels. They know these markets and have long-established relationships with these customers. We want to leverage these assets."

Since the mid-1980s, one common characteristic of almost every lab acquisition has been a high rate of lost client accounts after the sale. LabCorp is aware of this "acquisition curse." Like **Quest Diagnostics** after the purchase of **SmithKline Beecham Clinical Laboratories**, LabCorp is making retention and successful integration of BDL and PML a high priority.

What remains to be seen is how other California competitors react to these developments. A change of ownership has traditionally been an opportune time for competing lab sales reps to woo away major accounts. There may be some interesting sales wars yet to take place in Southern California. **TDR** Contact Al Lui, M.D. at 512-219-8020, Phillips I. Gausewitz, M.D. at 858-550-3223, Al Troub at 858-658-6401, and Pam Sherry at 336-584-5171.

INTELLIGENCE

LATE & LATENT

Items too late to print,
too early to report



There's another healthcare E-commerce company starting up. This one's directed at the clinical laboratory industry. To be called "LabPortal.com," it's connected to **Golder, Thoma, Cressey, Rauner Inc., Park City Solutions, and American Medical Laboratories.** LabPortal.com will be managed by Mark Johnston, who left an executive post at LabCorp to join the new firm.

Digene Corporation's Hybrid CaptureR II HPV test was named "Biotechnology Product of the Year" for 2000 by the High Technology Council of Maryland. Because of Maryland's active biotech community, this is notable recognition for Digene's DNA-based diagnostic technology. Also, a point of correction is in order. In the March 27, 2000 issue, THE DARK REPORT stated that Digene's Hybrid Capture II HPV test used a blood sample. This is incorrect. It uses a sample of cervical cells, collected with the same devices used in Pap smear collection.

AP SAYS DOCTORS "MORE DANGEROUS" THAN GUN OWNERS

Here's an interesting item that demonstrates how statistics can be misleading. The *Associated Press* (AP) reported recently that the 700,000 physicians in the U.S. "cause" 120,000 accidental deaths per year, generating a ratio of accidental deaths per physician of 0.171. The number of gun owners in the U.S. is 80 million, and there are 1,500 accidental gun deaths per year for all age groups. Thus, the accidental deaths per gun owner is 0.0000188. The AP writer noted that these statistics would indicate that doctors are 9,000 times more dangerous than gun owners!

SMS GETS ACQUIRED

Maybe **Shared Medical Systems** (SMS) really was for sale. After pooh-poohing a tender offer from Eclypsis, led by ex-SMS CEO Harvey J. Wilson, it was announced on May 1 that **Siemens AG** would acquire SMS for \$2.1 billion. Siemens' wants to combine its magnetic resonance imaging and X-ray equipment business, which

generates data on patients, with the information network products offered by SMS.

AN IMPENDING MARRIAGE?

Some interesting rumors, as yet unconfirmed, are making the rounds. In the pathology world, scuttlebutt says that two pathology companies with national ambitions are negotiating a merger or acquisition. If true, expect official news to surface within 30 days.

AND A DIVORCE, TOO?

On the divorce front, THE DARK REPORT has always noted that hospital lab-commercial lab business relationships are fraught with pitfalls. Anytime the financials become weak, both parties have an incentive to dissolve the relationship. Some lab industry observers believe that may be the case with a rather high-profile relationship between one hospital company and a laboratory company. Details of the situation remain fuzzy, but word is that the financial outcomes of this particular enterprise are leading both parties to seek an honorable way to dissolve the project and go their separate ways.

***That's all the insider intelligence for this report.
Look for the next briefing on Monday, May 29, 2000.***

PREVIEW #7

EXECUTIVE WAR COLLEGE

May 16-17, 2000 • Fairmont Hotel • New Orleans

Topic: What's Ahead for HEDIS and Laboratory Test Reporting at HMOs

Here's a War College exclusive! For the first time, a representative from the National Committee for Quality Assurance (NCQA) will address a national laboratory meeting. Learn first-hand about how HEDIS reporting requirements are developed and expanded from year to year and what's ahead for the lab industry in 2001 and 2002.

***Full program details available by calling 800.560.6363
or visit darkreport.com***

UPCOMING...

- ***Inside News From the Fifth Executive War College in New Orleans.***
- ***How Web-based Test Ordering and Reporting is helping a Chicago Hospital Lab's Physicians.***
- ***New HMO Lab Contracts and Capitated Rates in California Evolve in Surprising Directions.***
- ***More Sales of Independent Labs Expected as Older Lab Owners Prepare to Exit the Business.***