

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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R. Lewis Dark

Founder & Publisher



Who “Runs” the Lab Industry?

HAVE MOST OF YOU EVER THOUGHT ABOUT WHO “RUNS” THE LAB INDUSTRY? This is a serious question! Who is responsible for teaching lab managers what is necessary to run a productive, profitable, and stable laboratory organization?

After all, laboratories in 1999 look very different than they did in 1989 or 1979. This is true whether it is a hospital-based laboratory or a commercial laboratory. You can see the changes. Assays are different. New instruments and new technology can be found everywhere. The organizational structure of laboratories has evolved in ways unimagined ten years ago.

I ask the question about who “runs” the laboratory industry for a reason. During the 1990s, I have been disappointed to see the turmoil, disruption, and misery caused as commercial lab and hospital lab consolidation wiped out thousands of jobs, upset tens of thousands of doctors, and made laboratory medicine a very stressful profession.

Obviously, as an industry, laboratorians certainly did a poor job of anticipating the future and preparing for it. The fat and prosperous years of the 1980s and early 1990s certainly lulled a number of lab executives and administrators asleep. They missed important signs that would have helped them weather the storms of managed care, declining reimbursement, and clinical integration. Whoever was “running” the lab industry during those years certainly let all of us down. We were not equipped with the success models necessary to guide our laboratories safely through the trials and tribulations that have shaken all of healthcare down to its very foundations.

I would suggest that the people “running” the lab industry *today* are those individuals who’ve cracked the code and combine enlightened management methods with strong leadership skills. They operate laboratories which are dynamic and productive places to work. We need to pay closer attention to them and learn what they can teach us.

American Medical Laboratories is one such place. As you’ll read on pages 2-8, its leaders have created a spirited, motivated laboratory organization that is growing rapidly. This growth creates job opportunities for its employees and enhanced services for physicians and patients. These are precisely the benefits that all lab managers want to offer their own employees, clients and patients. The challenge is for all of us to learn how to create a similar climate of stability, confidence, and success for our own laboratory!

Client Service and Sales Fuel Fast Growth at AML

New owners at American Medical Labs turbocharge a venerable lab company

CEO SUMMARY: *Here's proof positive that effective management can make a positive difference in the financial performance of clinical labs. Upon taking title to American Medical Laboratories in the spring of 1997, its new owners used an emphasis on "customer-first" service and aggressive sales to transform the lab operation into a fast-growth revenue engine, doubling annual sales in just 30 months!*

In just two years, new owners of **American Medical Laboratories (AML)** have made it probably the fastest-growing clinical laboratory operation in the United States.

Based in Chantilly, Virginia, just across the Potomac River from Washington, DC, AML is rapidly morphing from a regional provider of testing to doctors' offices and hospitals into a credible national reference laboratory.

Many clients of **THE DARK REPORT** on both coasts can attest to this fact. AML sales reps and executives have swarmed into their laboratories, telling the AML story, asking for the business, and developing new relationships. An increasing number of hospital laboratory administrators are touring AML's Chantilly headquarters

and lab to learn more about the "new" reference laboratory source.

To become a nationally-recognized reference laboratory, AML's management team is juggling multiple priorities and pushing change into the organization at a rapid rate. One measure of AML's progress is revenue growth. As a private company, AML does not release financial information. But its executive team does state that revenues will have doubled between spring 1997 and the end of this year.

THE DARK REPORT estimates that AML's annual revenues were about \$75 million going into 1997. If this number has doubled, then AML has grown to \$150 million! That would make it one of the 10 or 15 largest independent laboratories still operating in the United States.

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Such an achievement, coming at a time when many big laboratories have been shrinking and posting significant losses, is one reason why laboratory executives should learn more about the business philosophies and methods used to energize AML.

Business Opportunities

"Only after purchasing AML did we begin to understand the business opportunities that exist today in the clinical laboratory industry," stated Tim Brodnik, AML's President. "It turned out that AML had a unique combination of resources and infrastructure. We decided to build our strategic growth plan around those unique assets.

"What we found at AML was a double business," he continued. "On one hand, AML was a leading provider of lab tests to physicians offices throughout Northern Virginia and the Washington, DC area. It had a reputation for quality, high market share, and acceptable profits."

"On the other hand, AML also had a major business in hospital reference testing, focused along the central Atlantic seaboard states," added Brodnik. "Hospital clients were very loyal to AML. Within the markets served by AML, it was viewed as a quality lab and a regional asset."

Unusual Business Strategy

AML used these two distinct business operations to formulate an unusual business strategy. "We viewed these testing businesses as the perfect hybrid," he noted. "We've established an integrated services model for laboratory testing. AML's laboratory services are supported by aggressive client service and promoted through an intense sales and marketing program."

According to Brodnik, AML will build upon three strengths in its bid to become a full-service national esoteric and reference testing laboratory. "One,

all testing is done from our single laboratory site in Chantilly," he said. "This helps us concentrate on technical and operational excellence.

"Two, our physicians' office testing business in Northern Virginia gives us direct experience in all aspects of laboratory testing and operations. We package this expertise and make it available to our reference clients. It's a source of added value we provide our clients and we use it to differentiate ourselves from competitors.

"Three, AML is situated near three major airports (Washington Dulles, Washington National, and Baltimore)," noted Brodnik. "We have access to excellent transportation resources and a favorable location relative to the entire United States."

Different Model For Lab

When Brodnik and his fellow buyers Jack Bergstrom and Jerry Glick first assumed control of AML in the spring of 1997 (*see TDR, May 12, 1997*), they created a very different model for laboratory services than those of competing labs.

"We describe our clients and customers as partners," stated Jack Bergstrom, Executive Vice President at AML. "We provide more than a simple menu of lab tests. We offer a full package of laboratory expertise to support client partners seeking to improve their own laboratory's technical, operational, and financial performance."

This concept of partnering helps AML's sales force distinguish its laboratory from those of competitors. "As we expand nationally, AML seeks a special kind of customer," explained Brodnik. "We don't want to simply put lower test prices on a piece of paper. That lasts only until a competing lab comes along and offers even lower prices.

"AML is interested in a special relationship with a special kind of

customer," he continued. "We want to have the right service to offer each laboratory customer as it responds to service needs in its own marketplace."

Long-Term Relationship

What Brodnik is describing is the concept of "long-term customer-supplier relationship" described by quality management guru W. Edwards Deming. Deming observed that a relationship built on adding value over the long term generated more profit for both supplier and customer than one based on low prices, renegotiated from contract to contract.

AML's strategy is to add value by leveraging its expertise with the physicians office testing segment of its business. "Typically, hospital-based laboratories are now operating within a multi-hospital health system," Brodnik noted.

"Effectively, this means they need a similar infrastructure as a regional commercial lab," he continued. "This includes a courier and logistics system, multi-site information system capabilities, outreach operations, sales and marketing, billing, collections, and multi-site management systems. AML offers its client-partners expertise in all these sectors.

"After all, our physicians office business in Northern Virginia means we must do these things every day. So our operations team can provide a variety of information, expertise and guidance to our hospital lab customers in these critical areas."

Brodnik and Bergstrom are describing a business model which positions AML differently than other sources offering reference testing to hospitals. They believe their market strategy will appeal to hospital lab administrators seeking more than simply the cheapest test prices.

On one hand, the national reference labs such as **ARUP Laboratories**, **Mayo Medical Laboratories**, and **Specialty Laboratories** offer quality reference testing, but are not as well-positioned to provide operational expertise in managing a regional hospital lab and its outreach sales program.

On the other hand, the three blood brothers, **Laboratory Corporation of America**, **Quest Diagnostics Incorporated**, and **SmithKline Beecham Clinical Laboratories** can offer this expertise, but they also compete with hospital laboratories for physicians' office testing.

American Med Labs At-A-Glance

- Laboratories in Chantilly, VA (250,000 sq. ft.)
- 33 Patient service centers.
- 7 Stat laboratories.
- Handling approximately 90,000 specimens per week.
- 300 Hospital clients.
- 1,300 Employees; 1,010 FTEs.
- 33 Marketing/Sales employees.
- 10 Field service reps and 40 in-house service representatives.
- SAMSA certified for toxicology testing.
- American Medical Laboratories offers clinical laboratory services in Maryland, Virginia, and District of Columbia.
- AML offers esoteric reference testing to hospitals and other laboratories nationally.

It has yet to be demonstrated whether hospital laboratory administrators will recognize this difference with AML. Further, laboratories mentioned above are fierce competitors for hospital reference testing. AML will be challenged in pursuing its goal of becoming a first-tier national reference laboratory.

Brodnik and Bergstrom have a well-deserved reputation for sales and marketing prowess. But that is not the full story behind AML's dynamic growth. The executive team at AML recognizes that operational excellence must accompany a professional sales and marketing program.

After all, why pay a sales rep generous commissions to bring in new business, only to disappoint those new clients with operational problems? That scenario is all too familiar to clinical lab sales reps.

AML's leadership is attempting to thwart that traditional weakness in lab operations. To accomplish this, they are empowering AML's staff to take responsibility for identifying problems and solving them. That is one reason for "measuring everything." Good information allows managers and staff to make good decisions.

Further, AML's executive team understands that people are what make a laboratory organization successful. That is why they manage people with the same intensity that most lab administrators manage technical processes.

In assessing what makes AML different from other laboratory organizations, there are probably five key management strategies underpinning the dynamic changes under way at this once tranquil laboratory.

First is the unequivocal commitment to meet and exceed the needs of customers. It's not just lip service, since first thing every morning the

lab's top executives meet with department heads to address even the most mundane of customer concerns.

Two, professional sales and marketing (which requires a significant investment of capital) takes AML's message directly to prospective clients. This gives AML control over its destiny.

Third, the company rigorously collects *accurate* and *timely* cost and productivity data, then uses it to drive intelligent decision-making.

Fourth, AML's leaders recognize that people are the real asset in the laboratory. Thus, they focus attention on managing people and motivating them to excel.

Fifth, AML's executive team stays close to both customers and staff. They are out on the road closing deals, supporting the sales process, and responding to customer concerns.

As Brodnik says, none of this is "rocket science." It is basic management which requires crisp execution to succeed. It is a formula which can be copied by any clinical laboratory willing to set aside old organizational politics and concentrate on managing fast growth and dynamic change.

S h o u l d American Medical Laboratories continue to profitably expand at the same rate as the last two years, it will demonstrate

that fundamental business principles, skillfully implemented, can generate financial success for clinical laboratories.

TDR

(For further information, contact Tim Brodnik and Jack Bergstrom at 800-336-3718.)

HEAR TIM BRODNIK AT EXECUTIVE WAR COLLEGE!

Tim Brodnik will do a special case study presentation about American Medical Laboratories at the upcoming Executive War College in New Orleans on May 11-12, 1999.

**Call for details or to register
800-560-6363**

Management Execution Part of AML's Success

*Good management execution supports
decisive leadership and shared vision*

CEO SUMMARY: *Swift and positive changes at American Medical Laboratories (AML) came as a direct result of energetic management. AML provides lab executives with an outstanding case study of how to take an existing, somewhat tranquil lab organization and turn it into a high-performance revenue machine. In the process, clients become winners, employees gain job stability, and the community benefits.*

Successful, dynamic business models for clinical laboratory operations are difficult to find in today's healthcare marketplace.

For that reason, changes under way at **American Medical Laboratories (AML)** in Chantilly, Virginia represent an outstanding case study in laboratory management.

Despite the challenges of falling reimbursement, declining utilization, and consolidation of providers, AML is posting strong growth to specimen volume, revenues, and operating profits. AML's performance demonstrates that clinical laboratories don't have to be a place of shrinking resources, service cutbacks and operational losses.

Arrival Of New Owners

The AML story begins with the arrival of its new owners in the spring of 1997. President Tim Brodnik explains. "AML was a lab that was under-marketed and under-capitalized. Its former owners, who remain active at AML today, recognized the need for a change, both in management philosophy and leadership style. What's happened since our arrival

is not management rocket science—it is doing simple things well.

"We introduced four key changes upon our arrival," noted Brodnik. "First, we measure *everything* in operations! This gives us performance benchmarks to monitor whether systems and people are improving."

"Second, we instituted a customer service meeting each morning at 9:00 a.m.," he continued. "This lasts under an hour and involves 40 to 50 department managers from every area of lab operations. We encourage swift action to resolve customer issues. More importantly, we use this meeting to revise internal systems and processes to prevent problems from recurring.

"Third, we expanded AML's sales team and changed compensation plans to reward profitable new business," said Brodnik. "This raised our visibility in the marketplace and stimulated a flow of new client accounts."

Fourth, AML made big investments in information resources and staff. Information will be a critical component of value-added lab services in coming years.

Jack Bergstrom, Executive Vice President at AML, explained why these changes had a positive impact on staff. "Measuring processes allowed people to see how they were improving. People like to succeed, and with good information they know exactly how their work is affecting outcomes."

"The daily customer service meeting is an opportunity for AML's team leaders to identify and respond to problems and communicate across all department boundaries," said Bergstrom. "On a daily basis, this meeting reinforces our philosophy of taking swift action to fix things or seize opportunities. The enthusiasm from this daily meeting spills out into the entire laboratory."

"Expansion of the sales program is critical to our expansion plans," he noted. "The market will not buy your services if they don't know who you are and what makes you different. Our sales team delivers that message and is responsible for adding new clients."

"Formerly, an AML sales rep was responsible for client service and new sales," added Brodnik. "Now a client service team handles ongoing needs for a client. The sales rep is pointed primarily toward generating new business."

"To reinforce this, we instituted a new sales compensation plan," he said. "This rewards the sales rep for profitable new business. These changes made it clear to everyone at AML that the objective was to focus on the customer and grow the business!"

AML's growth strategy is built upon the complementary execution of excellent client service and professional sales and marketing. The lab believes that if it can truly "outperform" competing labs with demonstrably better service, then it will scoop up more new business.

"Operating an error-free laboratory is a real challenge," explained Brodnik. "Mistakes happen in every laboratory. What has changed at AML is the attitude towards responding to problems which affect the client. Most labs talk about good service, but don't back it up with money, management time, and staff commitment. We are devoting significant resources to make sure that our service is recognizably better than that offered by competing laboratories."

Commitment To Customers

AML's commitment to a customer-focused organization is shared by its employees, and for good reason. "AML's former owners, Ira Godwin, M.D. and C. Barrie Cook, M.D., were always concerned about the welfare of their employees. That is one reason why they did not sell AML during the big acquisition wave of the 1990s," recalled Brodnik. "They didn't want to see this laboratory dismantled, specimens shipped elsewhere, and the employees laid off."

"We share the view of Godwin and Cook that people are the true resource of AML. We spend as much time managing people and supporting their personal growth as we do with customers and new clients," he said. "For a two-month period after our arrival, every employee in this organization was interviewed, individually or in groups, and invited to speak candidly about the company, their expectations, and their suggestions for improvement."

"These interviews, and the information gained from them, have been used to focus our efforts on building the type of company for which all employees can be proud," continued Brodnik.

What went unsaid by Brodnik and Bergstrom during this exclusive interview with THE DARK REPORT was a

Laboratory Sales and Marketing Costs \$'s, But is the Source of Laboratory Stability

HOW DOES A \$75 MILLION LABORATORY double in size in only 30 months? This is a remarkable accomplishment. Yet is it one that can be duplicated by other laboratories willing to invest in a professional sales and marketing program.

American Medical Laboratories (AML) understands the power of sales and marketing to sustain and strengthen a clinical laboratory. Since 1997, AML's sales force has grown by more than 50%, increasing the number of sales staff from 22 to 33. With more sales people in the field, the volume of new business can increase significantly.

Although commercial laboratories have maintained active sales programs for years, it has only been lately that an increasing number of hospital-based

laboratories have begun their own outreach sales programs.

It is important to understand that a professional laboratory sales and marketing program requires significant investment, both of money and of management time. It is not an activity which "manages itself."

Further, it is crucial that professionally-trained sales people be hired and put in the field. The best of these people have experience, training, and skills which reflect a lifetime of study, and contribute significantly to a successful sales effort.

Finally, it is important to let sales people sell, and not be distracted by customer service responsibilities. Their skills and attention should be focused on generating new client accounts for the laboratory.

discussion about the role of leadership and creating a shared vision.

It is no accident that American Medical Laboratories is now an energized, focused laboratory. It has an executive team that possesses competent leadership skills and uses them effectively.

Created A Vision

AML's leadership has created a vision of what the laboratory can become. It is teaching each employee how to understand that vision and how to contribute their part in making the shared vision into reality.

This requires intense people-management skills. But the rewards are immense. In the past 20 years, look at the growth of **Compaq Computers**, of **Microsoft**, of **Intel**. These are companies where people are excited to come to work. They

get support from management and share in the rewards of a successful, thriving business.

Only a handful of hospital laboratories and commercial laboratories operate along similar parameters today. Along with American Medical Laboratories, they understand the new paradigms for management, and are blessed with leaders willing to adopt these new paradigms.

In the case of AML, the ambitious goal of becoming a first-tier national reference laboratory can only happen if the combination of leadership, good management execution, and total employee commitment gel together. Any sustained success will be attributable to these factors. **TDR**

(For further information, contact Tim Brodrik and Jack Bergstrom at 800-336-3718.)

IMPACT OF LABORATORY CONSOLIDATION

1998 LIS Sales Rankings Show How Marketplace is Changing

CONSOLIDATION CONTINUED impacting sales of new laboratory information system (LIS) software during 1998.

Sales champs in THE DARK REPORT's annual ranking of the *Top Ten LIS Vendors* for 1998 are **Meditech** and **Fletcher Flora**, in the categories of LIS sales to hospitals and non-hospitals respectively. Rankings for 1998 performance demonstrate how the marketplace for LIS products is changing.

In the category of new sales of LIS to hospitals, Meditech placed 97 systems in 1998. Second were Fletcher Flora and **HBOC & Co.**, each placing 78 systems.

In sales to the non-hospital category, which primarily includes independent clinical laboratories, Fletcher Flora placed 118 systems, followed by second place **Schuyler House** (47 systems), and third place **Creative Computer** (16 systems).

In total installed systems, Meditech dominates the hospital category. It has 1,083 LIS systems in operation. This represents 20% of the nation's hospitals. Next is Sunquest, with 916 installed LIS systems and 17% of the nation's hospitals, then **Cerner Corp.** with 621 and 11.5%.

Among non-hospital systems, **Sunquest** is number one, with 227 LIS installations, or about 10% of the market. Number two and number three are

Creative Computer Applications (210 and 9.4%) and **Schuyler House** (200 and 8.97%).

One significant change from 1997 to 1998 was a decline in the number of non-hospital installations, from 2,552, to 2,231. This means the independent laboratory marketplace shrunk by almost 13% during the year. It demonstrates the impact that poor reimbursement and laboratory consolidation is having upon this segment of the lab industry.

THE DARK REPORT'S TOP TEN LIS VENDORS Hospital Sales (1998)

Rank	Company	New Sales 1998	Cumulative Sales	New Sales Per Cent	Cumulative Per Cent
1	Meditech	97	97	13.20%	13.20%
2	Fletcher Flora	78	175	10.62%	23.82%
2	HBO & Co	78	253	10.62%	34.44%
4	Sunquest	75	328	10.21%	44.65%
5	Cerner Corp	70	398	9.53%	54.18%
6	CPSI	47	445	6.40%	60.58%
7	Healthcare Mgt Systems	25	470	3.41%	63.99%
8	Dynamic Healthcare	20	490	2.73%	66.72%
9	Schuyler House	18	508	2.45%	69.17%
9	Citation	18	526	2.45%	71.62%

Total All (45) Vendors: Sales 735
Total 1997 new sales 660

100.00%

Provided by: R.L. Johnson & Associates

THE DARK REPORT'S TOP TEN LIS VENDORS Hospital Installations (1998)

Rank	Company	Total 1998	Cumulative Installed	Installed Per Cent	Cumulative Per Cent
1	Meditech	1,083	1,083	20.08%	20.08%
2	Sunquest	916	1,999	16.94%	37.02%
3	Cerner Corp	621	2,620	11.48%	48.50%
4	HBO & Co.	325	2,945	6.01%	54.51%
5	SMS	298	3,243	5.51%	60.02%
6	Isys/Biovation	250	3,493	4.63%	64.65%
7	Citation	240	3,733	4.44%	69.09%
8	SCC	195	3,928	3.61%	72.70%
9	CPSI	149	4,077	2.76%	75.46%
10	Creative Computer	140	4,217	2.59%	78.05%

Total All (45) Vendors: Installations 5,410
Total 1997 installations 5,153

100.00%

Provided by: R.L. Johnson & Associates

THE DARK REPORT'S TOP TEN LIS VENDORS Non-Hospital Sales (1998)

<u>Rank</u>	<u>Company</u>	<u>New Sales 1998</u>	<u>Cumulative Sales</u>	<u>New Sales Per Cent</u>	<u>Cumulative Per Cent</u>
1	Fletcher Flora	118	118	38.95%	38.95%
2	Schuyler House	47	165	15.52%	54.47%
3	Creative Computer	16	181	5.28%	59.75%
4	Isys/Biovation	6	187	1.98%	61.73%
5	Hex 'FF'	5	192	1.65%	63.38%
5	Intellidata	5	197	1.65%	65.03%
7	Dynamic Healthcare	4	201	1.32%	66.35%
7	Psyche Systems	4	205	1.32%	67.67%
8	Cerner	2	207	0.66%	68.33%
9	Five Vendors*	1	208	0.33%	68.66%

Total All (45) Vendors: Sales

303

100.00%

Total 1997 Sales

310

* Citation, Health Science Systems, New Lab Force, SCC, Triple-G each placed one new system.

Provided by: R.L. Johnson & Associates

As in past years, Pareto's Law continues to accurately describe the LIS industry. Generally the top five or six companies in each market segment control 50% or more of all sales activity. Ranking tables in this story show how a limited number of vendors dominate each category.

This LIS sales data is based on numbers compiled by consultant Robert Johnson of **R. L. Johnson & Associates**, who has collected hospital and medical information systems data annually for 16 years.

TDR

(For further information, contact R.L. Johnson at 209-839-8052.)

THE DARK REPORT'S TOP TEN LIS VENDORS Non-Hospital Installations (1998)

<u>Rank</u>	<u>Company</u>	<u>Total 1998</u>	<u>Cumulative Installed</u>	<u>Installed Per Cent</u>	<u>Cumulative Per Cent</u>
1	Sunquest	227	227	10.18%	10.18%
1	Creative Computer Applications	210	437	9.42%	19.60%
2	Schuyler House	200	637	8.97%	28.57%
4	Fletcher Flora	187	824	8.39%	36.96%
5	Isys/Biovation	161	985	7.22%	44.18%
6	Hex 'FF'	120	1,105	5.38%	49.56%
7	New Lab Force	100	1,205	4.49%	54.05%
8	Pysche Systems	43	1,248	1.93%	55.98%
9	SCC	39	1,287	1.75%	57.73%
10	Dynamic Healthcare	22	1,309	0.99%	58.72%

Total All (45) Vendors: Installations

2,231

100.00%

Total 1997 new Installations

2,553

Provided by: R.L. Johnson & Associates

Neuromedical Systems Files Bankruptcy Action

Manufacturer of the PapNet® system finally runs out of time and money

CEO SUMMARY: Automated cytology technology suffered its first financial failure. Escalating losses and dismal revenue prospects combined to drive Neuromedical Systems, Inc. into bankruptcy. Its PapNet System for Pap smears was a pioneering technology that never achieved market acceptance. Neuromedical's experience demonstrates that lab executives take a risk when they adopt new technology.

Faced with poor financial prospects and escalating losses, **Neuromedical Systems, Inc.** (NSI) filed Chapter 11 bankruptcy on March 26, 1999.

This is the first business failure among the firms pioneering automated cytology technology. It means that the combination of Neuromedical's technology, marketing strategy, and management implementation failed to secure a successful foothold in the healthcare marketplace.

Neuromedical Systems was the developer of the PapNet® system for diagnosing Pap smears. Since obtaining FDA approval to use PapNet as an adjunctive test for Pap smear screening in 1995, the company has struggled to carve a place for itself in the healthcare marketplace.

Filed Bankruptcy Action

NSI, based in Upper Saddle River, New Jersey, filed its bankruptcy action shortly after a similar filing in Europe. **NSI Netherlands, B.V.** is NSI's European division. It obtained a court-mandated moratorium on March 16 to

evaluate business options, including bankruptcy. Business operations in Germany have also ceased.

The impact of NSI's bankruptcy action upon clinical laboratories using PapNet is difficult to assess. Calls to NSI's corporate offices went unanswered as of press time.

Centralized Pap Screening

PapNet was originally introduced into the marketplace as a centralized screening center. Labs sent Pap smear slides to NSI's central laboratory. The slides were scanned and PapNet used software algorithms to identify the 128 cells most likely to be abnormal.

These pictures and the original slide were returned to the referring lab. There a cytotechnologist would evaluate PapNet's highlighted 128 cells to determine if manual rescreening was needed.

Critics of the system pointed out that most laboratories do not want to ship slides to a national center and wait to have them returned. NSI responded by developing a more sophisticated PapNet system, dubbed PAPNET-on-Cyte. This

version of PapNet was installed at the customer's laboratory, where both screening and diagnosis would be done on site. This gave the laboratory more control over the process.

Double-Screening of Paps

One early proponent of the PapNet system has been **Associated Pathologists Laboratories (APL)** of Las Vegas, Nevada. It operates a PAP-NET-on-Cyte instrument in their central laboratory. APL has a standing policy of manually double-screening 100% of its Pap smears. With PapNet approved as an adjunctive test, APL found it to be a cost-effective solution to give its patients the option of a third screen by PapNet.

"As Neuromedical notified us of their financial situation, we've worked out an arrangement to continue using the PapNet system," stated John Schwartz, President and CEO of APL. "We've hired their technician and continue using the instrument as before.

"I do not know what lies ahead for NSI," added Schwartz. "When we originally evaluated the various automated cytology technologies, one of our concerns was about the viability and staying power of these start-up companies. This certainly demonstrates the risk of being an early adapter of new technology."

Huge Amounts of Capital

One person who agrees with Schwartz is Alan Nelson, Ph.D., Chairman of **NeoPath, Inc.** in Redmond, Washington. "It requires huge amounts of capital to develop automated cytology technology and introduce it into the marketplace.

"During the corporate life of Neuromedical Systems, they went through over \$170 million of investors' money, if you include venture capital financing and subsequent stock offerings," he noted. "At NeoPath, we've

raised over \$150 million from investors and are only now approaching a point of break-even cash flow.

"The other cytology company in the U.S. marketplace is **Cytec Corporation**, makers of the ThinPrep monolayer Pap smear preparation system," added Dr. Nelson. "Cytec has also gone through about \$160 million of investor funding. It was only at the end of last year that Cytec posted its first quarterly profits."

Indications are that Neuromedical Systems will cease operations and exit the automated cytology business. It is selling its intellectual property, patents, and other assets to **AutoCyte, Inc.** of Burlington, North Carolina. (See related story, pages 14-15.)

"I do not know what lies ahead for NSI," added Schwartz. "When we originally evaluated the various automated cytology technologies, one of our concerns was about the viability and staying power of these start-up companies."

It is estimated that less than 20 PapNet systems are in operation around the world, including the United States, Europe, Hong Kong, and Taiwan. Like Associated Pathologists Laboratories, current users will develop their own solutions to NSI's bankruptcy.

The bankruptcy of Neuromedical Systems is a reminder that automated cytology technology remains a high risk business. Lab executives should exercise caution when selecting a vendor to provide automated cytology systems in their laboratory.

TDR

(For further information, contact John Schwartz at 702-733-7866 and Alan Nelson, Ph.D. at 800-636-7284.)

AutoCyte to Buy NSI's Patents and Other Assets

FDA gives favorable review to firm's data on its Pap smear PREP® system

CEO SUMMARY: When Neuromedical Systems entered Chapter 11 bankruptcy, AutoCyte moved rapidly to purchase Neuromedical's patents and other intellectual property for automated cytology technology. Even as Neuromedical disappears from the marketplace, AutoCyte is preparing its entry. Laboratories will soon have a new brand of automated cytology technology to evaluate for purchase.

EXECUTIVES AT AUTOCYTE, INC. acted quickly when given the opportunity to purchase patents, intellectual property, and other assets of **Neuromedical Systems, Inc.®**, manufacturer of the PapNet system for Pap smear screening.

Subject to approval of the bankruptcy court, AutoCyte will pay \$4 million in cash and 1.4 million shares of AutoCyte stock to acquire the crown jewels of Neuromedical Systems: its automated cytology patents. With AutoCyte stock currently at about \$6 per share, total value for the deal is \$12.4 million.

AutoCyte has developed automated systems for monolayer preparation of Pap Smears (called PREP®) and cytologist-assisted diagnosis of Pap smears (called SCREEN®). The company is awaiting FDA approval for its PMA applications covering both automated cytology systems.

AutoCyte was recently notified by the FDA that its clinical data for the PREP system had been successfully reviewed. Once final details

about labeling and other issues are settled between the FDA and AutoCyte, it is expected that the FDA will issue an approval and AutoCyte's PREP system can then be sold in the marketplace.

Meanwhile, Neuromedical's bankruptcy triggered swift action by AutoCyte. "We are interested in build-

What sets AutoCyte apart from other automated cytology companies is its goal of developing an integrated suite of Pap smear preparation and screening instruments.

ing our patent estate," said James Powell, M.D., President and CEO of AutoCyte. "Neuromedical developed a number of patented technologies in Pap smear screening. We believe these will complement our own research efforts."

What sets AutoCyte apart from other automated cytology companies is its goal of developing an integrated

suite of Pap smear preparation and screening instruments. AutoCyte's PREP and SCREEN systems are designed to complement each other.

"Our original concept was that high volume cytology laboratories would benefit from automation," explained Dr. Powell. "We started from the premise that a monolayer preparation would reduce variability when imaging the Pap smear, thus enhancing the productivity of automation.

"The monolayer preparation eliminates extraneous material on the Pap smear slide," he continued. "This means that an automated screening device finds consistent information on the Pap smear slide which is of a better quality for diagnosis."

Monolayer Pap smears

For this reason, AutoCyte designed its SCREEN system to handle monolayer Pap smears. AutoCyte would like to have the flexibility in the future of accommodating the wide variation of traditional Pap smear stains.

"This was a significant problem which Neuromedical Systems had to solve with its PapNet system," said Dr. Powell. "It had three years experience in capturing data from conventional Pap smear slides prepared by a number of laboratories around the world. Acquiring its patents, including the neural net technology, gives us access to that experience and the technology refinements it built into its system.

PREP To Hit The Market

With final FDA approval on the PREP PMA expected within just a few months, AutoCyte is preparing to introduce its version of a monolayer Pap smear preparation system into the marketplace. As it comes to market, it will benefit from the new CPT codes for liquid Pap smear preparations that became effective on January 1, 1999.

AutoCyte & NeoPath Seek FDA Supplement

AutoCyte and NeoPath announced on March 23 that the two companies will jointly develop clinical trials to demonstrate the effectiveness of AutoCyte's PREP system with NeoPath's AutoPap system for the primary screening of Pap smears.

"It has always been our goal to maintain AutoPap as an open system," stated Alan Nelson, Chairman of NeoPath. "Now that the FDA has successfully reviewed clinical data for AutoCyte's PREP system, we expect approval of their PMA will be forthcoming. It is logical timing to now invest resources to demonstrate that both company's systems work effectively together in the preparation and primary screening of Pap smears."

"It is a positive sign that improved reimbursement for Pap smears is impending," said Dr. Powell. "The new CPT codes will have a beneficial effect for laboratories that want to acquire and use automated cytology systems."

AutoCyte's PREP system will compete with **Cytec Corporation's** ThinPrep® system, while its SCREEN system will compete with **NeoPath Inc.'s** AutoPap® Primary Screening System.

Laboratory executives and pathologists should expect to see ongoing improvements in the diagnostic accuracy and the cost-effectiveness of automated cytology technology. Competition, technological advances, and clinical experience will generate steady gains in the performance and effectiveness of these automated cytology systems.

TDR

(For further information, contact James Powell, M.D. or Elizabeth Long at 800-426-2176.)

The Dark Index

Unilab, DIANON Systems, UroCor Report 1998 Financial Results

OPTIMISM REIGNS at California-based **Unilab Corporation**. Revenues are up, operating profits are increasing, and company officials are now talking about growth plans.

For 1998, Unilab generated revenues of \$217.4 million, compared to \$214.0 million in 1997. Its acquisition of bankrupt **Meris Laboratories** late in 1998 accounted for some of the revenue growth. (*See TDR, September 28 and November 9, 1998.*)

Real News At Unilab

What is real news at Unilab is its net income for the year, reported at \$11.9 million. This stands in contrast to the past three years, when Unilab eked out a teensy \$0.5 million profit in 1997, posted a huge \$92.9 million loss in 1996, and a considerable loss of \$42.7 million in 1995.

Unilab's accomplishment is significant. Unilab is the dominant commercial laboratory in California. As such, its financial performance can be considered a bellwether for that state's laboratory marketplace. If Unilab is on the road to financial recovery, it may be a valid sign that the laboratory marketplace has finally hit bottom in the state.

Unilab's President and CEO, David Weavil, seems to agree. In public statements he characterized 1998 "as a defining one for Unilab...especially defining was our decision to establish new growth objectives following a 1 1/2-year period dedicated to improving our operating platform."

Translating that quote into plain English, Weavil is declaring that Unilab is ready to pursue a growth strategy. That stands in contrast to the last couple of years, when Unilab was forced to focus almost exclusively on internal operations and cost-cutting programs.

Growth requires additional testing volume, so Unilab's sales and marketing activities should be expected to intensify. As this occurs, lab competitors will be watching to see if Unilab is willing to return to its past habits of bidding for new managed care contracts using marginal cost pricing.

In the heyday of Andrew Baker, Unilab's former President, the company was willing to bid incredibly low prices to acquire new streams of specimens. Aggressive sales and equally aggressive pricing did make Unilab the largest clinical laboratory operation in California. But one consequence of Unilab's influence on laboratory pricing levels was to make California an unprofitable market for laboratory testing.

Shipping New Systems

A similar wave of positive developments is fueling revenue growth at **DIANON Systems, Inc.** in Stratford, Connecticut. Its fourth quarter revenues were \$16.1 million, the highest quarterly revenues ever recorded at the company. This was a 9.6% increase over fourth quarter, 1997.

Total revenues for 1998 were \$62.2 million, a 2.1% increase over the previous year. However, despite increases to

revenue, DIANON saw net income for both fourth quarter and the full year decline from 1997 levels.

Pathologists will be interested to learn that anatomic pathology (AP) is becoming the revenue growth engine at DIANON. During the fourth quarter, AP services accounted for 75% of DIANON's revenue base.

Emphasize Anatomic Path

Several years ago DIANON began emphasizing anatomic pathology as a way to diversify its dependency on clinical testing. During 1998, the company achieved several important milestones in its efforts to expand anatomic pathology services.

First, it joined a limited provider panel under contract with **Quest Diagnostics Incorporated** to provide anatomic pathology services to members of **Oxford Health Plans**.

Second, it has sought to acquire pathology practices that support its corporate growth strategy. In December DIANON announced an agreement to purchase **Kyto Meridien Diagnostics, LLC**, a \$13 million OB/GYN lab in New York. (*See TDR, January 11, 1999.*)

DIANON President and CEO Kevin Johnson is optimistic that these developments will contribute to improved revenues and profits this year. He states that corporate initiatives "could facilitate 1999 top-line growth in excess of 20% and EPS [earnings per share] improvement of over 30%."

Clinical Milestones Ahead

At **UroCor, Inc.**, 1998 has been a trying year. Although it saw healthy gains in revenue, profits were elusive. UroCor is a disease management company which offers diagnostic testing and other services to urologists throughout the United States.

Full year revenues for 1998 increased by 44.5%, from \$33.0 mil-

lion in 1997 to \$47.6 million in 1998! Strong revenue growth went unmatched by profits. UroCor reported a net loss of \$2.5 million for 1998, which included \$8.2 million in special charges during the course of the year.

Clients of THE DARK REPORT are familiar with UroCor. During the 1990s it has been a fast-growth company with a sustained track record of success.

Setbacks in 1998 were the result of product initiatives which did not do as well in the marketplace as expected. UroCor was also investing money to expand its sales force and teach it how to market therapeutic products to physicians.

This is one aspect of UroCor which clinical laboratory executives should track. The company is pushing steadily to integrate therapeutic drugs into its product line. It believes that urologists will find it a benefit to obtain both diagnostic tests and therapeutic products from a single source.

Integrated Clinical Care

This is in line with the trend toward integrated clinical care. If UroCor can figure out a method to successfully marry diagnostic testing with therapeutic products, it may well create a new business model for the next generation of clinical laboratories.

Taken collectively, the 1998 financial performance of Unilab, DIANON Systems, and UroCor indicate that the marketplace is turning around. Financial uncertainty seems to be fading, replaced by optimism and hopeful plans for growth.

As reported in the last issue of THE DARK REPORT, the three blood brothers reported similar positive financial news. Collectively, this may be a sign that all laboratories are well advised to respond to these positive market trends with growth strategies of their own!

INTELLIGENCE

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



As consolidation of hospital ownership goes, so goes laboratory consolidation. The big trend driving consolidation of hospital ownership is the formation of integrated healthcare systems (IHS). According to **SMG Marketing Group**, a Chicago-based healthcare information and marketing company, there are now 604 IHS, a number which *increased by 40%* between 1995 and 1998! More importantly, the rate at which hospitals are joining systems increased at twice the rate. SMG says that 3,760 hospitals were in systems by January 1999, an *83% jump* from 2,060 hospitals in April 1995.

ADD TO...INTEGRATED HEALTH SYSTEMS

This migration into integrated health systems is a phenomenal trend and so new that the pace of hospital laboratory consolidation should continue at a fast clip. This will affect employment levels in the lab industry. It will also change the way reference laboratories, software vendors, and diagnostics manufacturers sell their products to hospital-based laboratories.

PRUDENTIAL TO REIMBURSE FOR AUTOPAP

Chalk up another win for **NeoPath, Inc.** in its bid to gain acceptance for its automated technology. On March 17 it was announced that **Prudential HealthCare**, one of the nation's largest health insurers, will offer reimbursement for the Auto-Pap® Primary Pap Smear Screening System.

MORE ON...AUTOMATED CYTOLOGY

NeoPath Chairman Alan Nelson tells **THE DARK REPORT** that the new CPT codes for automated Pap smear procedures are having a positive impact. Three months into the new year, he reports that the payments for the claims submitted early in the year are starting to show up. Reimbursement levels for the new CPT codes are ranging from \$12 to \$45. If this trend bears out through the course of the year, it will improve the economics of acquiring and using automated Pap smear technology.

Remember the hoopla about Herceptin® as a therapeutic

for metastatic breast cancer? There is a diagnostic side to this story. Recently **Genentech, Inc.** and **IMPATh, Inc.** agreed that IMPATh will provide "information services and analytical services relating to breast and other cancers that may benefit from treatment with Herceptin." IMPATh is now positioned for a double benefit. First, it will be paid to provide data to Genentech from its databank of 450,000 analyzed cancer cases. Second, IMPATh naturally becomes a preferred source for diagnostic tests. IMPATh can make money from both dimensions of the relationship. This is also a market transaction based around pharmacogenomics. (See **TDR**, September 8, 1998).



Joint Purchasing Corporation (JPO)

selected **Specialty Laboratories** of Santa Monica, California to be a clinical laboratory service provider. The contract, effective March 1, 1999, gives Specialty access to JPO's 800 hospitals, most of which are located in the Northeast United States.

*That's all the insider intelligence for this report.
Look for the next briefing on Monday, April 26, 1999*

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