

*From the Desk of R. Lewis Dark...*

# THE **RD** DARK REPORT

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

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**R. Lewis Dark**

**Founder & Publisher**



## ***Clinical Labs Discover Benchmarking***

IN OUR MANY YEARS OF SERVICE to the clinical lab industry and the pathology profession, THE DARK REPORT has consistently been first to identify important trends and explain their relevance to those responsible for managing the nation's laboratories.

Back in 1995, we predicted that the (then) three blood brothers would strive to obtain exclusive managed care contracts with the nation's largest health insurers, but that the challenges of properly servicing these contracts and making money would prove to be daunting. Certainly the big national contracts signed by **SmithKline Beecham Clinical Laboratories** at marginal-cost pricing played a key role in its eventual sale to **Quest Diagnostics Incorporated** in 1999.

In 1997, we were first to tackle the reality of total laboratory automation (TLA). Vague and unsupported public pronouncements made by many vendors and their first-generation clients in lab meetings and seminars made it seem like TLA was *the* wave of the future for progressive labs. It was the THE DARK REPORT that challenged this perception and demonstrated that the earliest TLA installations were struggling to fulfill the financial and operational expectations established in advance. Many clients and readers of THE DARK REPORT have thanked us for helping them understand the limitations of TLA technology at that time.

In 1998, THE DARK REPORT was first to publicly connect the tidal wave of hospital mergers and acquisitions to the subsequent consolidation of hospital laboratories. This analysis allowed many shrewd lab administrators and pathologists to better position their lab organization for the inevitable consolidation projects that were pushed upon them.

In 2002, THE DARK REPORT will cover an important, still-evolving trend in clinical laboratory management. It is performance bench-marking. Hospital lab administrators and pathologists are turning to a variety of new tools for measuring operational performance and the quality of services provided, both in the integrity of test results and how lab customers perceive the lab's performance. For all of us here, this is welcome news. It is another step forward in the management sophistication of the clinical lab industry. Increasingly, the nation's lab leaders are willing to look for management tools used outside healthcare. That can only lead to further improvement in how clinical laboratories are organized and deliver testing services.

# Path Trends For 2002 Show Future Direction

*Our biannual pathology profession review reveals which market forces are at work*

By Robert L. Michel

**CEO SUMMARY:** *Even as pressures to squeeze costs and consolidate within the pathology profession ease, a different set of market trends is exerting influence. Collectively, these trends portend the end of the small pathology group's dominance of its local healthcare marketplace. It will become increasingly important for successful pathology groups to offer a full range of pathology subspecialty expertise.*

IT MAY BE A RELATIVELY QUIET TIME in the pathology profession, since pressures to consolidate and regionalize have eased and most pathology groups are financially stable.

Certainly in the two years since THE DARK REPORT published its last comprehensive list of pathology trends, most pathology group practices now face a friendlier healthcare environment. But it would be wrong to characterize this quiet period as a time when marketplace changes have slowed.

To the contrary, although the six pathology trends presented in this issue are not expected to exert noticeable pressure on pathology groups in the short term, several of these primary trends will play out in the marketplace in complementary ways.

For example, the emergence of national pathology firms causes them to recruit "world class" pathologists and advertise that fact. That reinforces the growth of pathology centers of excellence. In turn, both of these trends play directly to the heightened interest of consumers, who are searching for best-of-class pathologists to review their case. Improvements in the Internet and telepathology enable consumers (and their physicians) to interact more effectively with pathologists located miles away.

Thus, although these six pathology trends may be "slower-acting" than market trends in the 1990s, their impact will be no less profound on how pathologists organize their practices and deliver clinical services.

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Key Trend

State of the Pathology Profession

no. 1

▶ **National Pathology Firms**20  
02

**N**ATIONAL ANATOMIC PATHOLOGY (AP) firms are a relatively new phenomenon in the pathology marketplace. But their rapid growth and solid financial success is demonstrating the validity of their business model.

In simplest terms, a national anatomic pathology company is one which operates a limited number of centralized pathology labs and feeds these labs with specimens originated from all regions of the United States. The two best-known examples of this business model are **DIANON Systems, Inc.** and **IMPATh, Inc.**, both publicly-traded. Another fast-growing player using this business model is **USLabs, Inc.**, based in Newport Beach, California and still a private company.

In a similar fashion, the regional networks of pathology laboratories operated by **AmeriPath, Inc.**, **Laboratory Corporation of America** and **Quest Diagnostics Incorporated** do a significant volume of pathology business. All three companies have one or more “core” AP labs capable of serving the national marketplace.

Collectively, these companies are actively reshaping the anatomic pathology (AP) profession. Through aggressive sales and marketing efforts, they are convincing office-based physicians that sending AP specimens to an out-of-area laboratory is as good an option, if not better, than referring those specimens to the pathology group based in the neighborhood hospital.

Earlier this year, THE DARK REPORT noted that it took only five

years for **DIANON**, **IMPATh**, and **AmeriPath** to achieve combined annual revenues in excess of \$600 million. This is not only a remarkable accomplishment, but irrefutable proof that office-based physicians are willing to shift their referral patterns away from local pathology groups. Pathologists should consider this to be a market shift of seismic proportions. Historically, local anatomic pathology groups have dominated the clinical marketplace.

THE DARK REPORT believes that the concept of “national anatomic pathology services” will continue to grow for many reasons. New technologies in molecular and genetic diagnostics, along with enhanced informatics and communications capabilities, will make it easier for physicians to use pathology labs located anywhere in the United States.

But economics is the trump card which will fuel this trend. The ample profits earned by this first crop of national anatomic pathology companies is leading to further investment by these companies in the resources they need to expand their market share. Here is what separates the national path companies from the local AP group practices.

The national AP companies are willing to invest capital to build their business. Local AP groups want to protect existing profits and are reluctant to invest their capital into new technology, sales and marketing programs, and sophisticated management systems. For that reason, many local pathology groups will see their share of their regional market eroded by the national AP firms.

Key Trend

State of the Pathology Profession

no. 2

Consumers Find Pathology

20  
02

**C**ONSUMERS REPRESENT a powerful new force in the national marketplace for anatomic pathology services.

During the past three years, consumer use of the Internet to seek healthcare information has become the number one use of the Internet. This development is an early warning message to anatomic pathologists and lab administrators. Consumers are hungry for information about quality healthcare.

Pathologists already have firsthand evidence of increased consumer interest. During site visits to pathology groups around the country, THE DARK REPORT regularly hears of stories about patients telephoning the pathologist who signed out their case to get more details about their diagnosis.

This happens because the attending physician is giving the patient a copy of his/her pathology report (which, in and of itself, is a change from customary practices in earlier years) and the patient takes the initiative to call the pathologist. Because many pathology cases involve a serious disease, the patient is motivated to learn, directly from the diagnosing pathologist, the salient facts about his/her medical condition.

Improvements in the presentation of pathology reports in recent years is further evidence of the influence of consumers on the pathology profession. Color pictures, better charting, and more readable formats are a direct result of physician and patient needs. **DIANON Systems, Inc.** has used its CarePath™ system of physician, patient, and payer

reporting to gain contract status as an AP provider with a growing number of the nation's largest health insurers. (See TDR, December 17, 2001.)

Another sign of greater consumer involvement in healthcare is the failure of the closed-panel HMO to satisfy middle-class Americans. Consumers want to have control over their healthcare. They want access to the best physicians and they want the ability to get second and third opinions. Closed-panel HMOs denied consumers these benefits. It should surprise no one that managed care is abandoning that business model and developing more consumer-friendly health plans.

To capitalize on this trend, anatomic pathologists need to make themselves more visible to the consumer. One way local pathology groups can do this is by establishing a Web site. As noted earlier, the Internet is becoming the first place that growing numbers of consumers begin their search for information and quality providers when they, or their loved ones, become ill.

THE DARK REPORT believes that increased consumer involvement in their healthcare is a trend that will encourage and support the development of national pathology companies. This, combined with the national pathology company's need for continual growth, will stimulate a variety of new pathology services that add value to physicians, payers, and, most importantly, consumers. It demonstrates why the healthcare market will not be static. It will continue to evolve in a dynamic way.

Key  
Trend

State of the Pathology Profession

no. 3

Path Centers of Excellence

20  
02

**M**OST OF THE PATHOLOGY TRENDS presented in this issue of THE DARK REPORT are contributing to the creation of regional and national pathology centers of excellence.

To be a center of excellence, a pathology group will need to provide clinical services which are recognized to be above the norm. To further reinforce their standings as centers of pathology excellence, these groups will try to recruit top-rank pathology subspecialists in as many clinical areas as possible. Market competition will drive this phenomenon.

That will be particularly true of national pathology companies. They need to develop professional expertise which they can claim is better than that found in most localities. This is their motivation to hire world-class specialists in specific areas of pathology, then advertise that fact to physicians, patients, and payers. (See the *AmeriPath* item on page 18 about Dr. Petras.)

On the consumer side, patients are looking for “best-of-class” physicians to add to their care team. Because many pathology procedures are integral to the accurate diagnosis of disease, it should be no surprise that growing numbers of consumers are willing to search for who they think is the nation’s “best” pathology sub-specialist in order to have their case referred for an additional professional opinion.

New technology is another trend which encourages pathology centers of excellence. It takes money and special expertise to acquire and offer new diagnostic

procedures. Because some diseases are uncommon, to economically offer the related procedures requires access to larger populations. Thus, a regional or national pathology center of excellence has the best ability to capture enough specimens to make that line of testing profitable.

Of course, enhanced informatics and the Internet make it easier and cheaper for a physician (and his/her patient) to refer a case to an out-of-area pathology subspecialist. Teleconferencing and telepathology systems provide the necessary tools to allow effective communication between the parties. This trend also supports the development of more pathology centers of excellence.

Where does this leave the small pathology group practice which is known for its generalist skills and serves its local healthcare market adequately? If all the tea leaves are assembled and read correctly, the healthcare market is evolving in ways that will put smaller pathology groups at a competitive disadvantage.

To retain its position within the local healthcare community it serves, the small pathology group is going to need to identify its specific areas of expertise, then develop affiliations with other pathology groups in the area that have complementary areas of clinical expertise.

Strategically, market demand for pathology services will shift toward specialization, thus favoring pathology centers of excellence. Increased market share will go to those pathology groups, whether small or large, which respond to the new needs of this changed healthcare marketplace.

Key Trend

State of the Pathology Profession

no. 4

**Molecular/Genetic Path**20  
02

**E**VERYBODY KNOWS IT'S COMING! Molecular- and genetic-based pathology services are heading for the clinical marketplace. The only question is: when?

THE DARK REPORT wants to emphasize a different transformational aspect of this technology. Most pathologists understand the range of clinical benefits that will result from scientific breakthroughs in these disciplines. But few pathologists have given much thought to how the profession will be changed by these same technologies.

THE DARK REPORT believes that a golden age for pathology lies just around the corner. Assays based on new molecular and genetic technologies will require pathologists to contribute more time and more expertise in helping referring physicians diagnose and treat patients.

At its simplest level, this should mean increased revenues for pathology groups which invest in these new technologies and develop the skills necessary to deliver a high quality of clinical support.

Although this sounds easy, it will be challenging for many pathologists. The current practice model is designed to support a pathologist who spends most of the time looking through a microscope and preparing reports to be read by the referring physician.

The new practice model will require lots more interaction with the referring physician. This will include help in ordering appropriate tests, active consultation in evaluating the results, and input on determining follow-on tests or therapies. Ongoing consultations involving

the monitoring of patients over time will also be included in the new pathology practice patterns.

Accept this premise and it becomes clear that traditional practice patterns in pathology are going to give way to a more collegial, team-type of interaction with referring physicians. Individual cases will become more complex and time-consuming, both in the actual testing itself, as well as the involvement with physician (and probably patient).

There are several early examples of this type of practice pattern. The evolution in the diagnosis and monitoring of leukemia and lymphomas, breast cancers, and HIV reflect this type of clinical practice model. The pathologist takes a more direct and active role in supporting the clinician. With certain patients, this role can continue for several years.

Accordingly, the challenge for the anatomic pathology profession is to understand the impact on molecular and genetic diagnostics at multiple levels: in clinical application, in operational execution, and in financial terms.

New diagnostics based on molecular and genetic technologies will require pathology group practices to invest their capital in different ways, to organize their pathology services in new models, and to respond to the different economics in a way that allows them to operate profitably.

This is the double-edged sword of pathology's coming Golden Age. One edge represents opportunity and profit. The other edge represents change and risk.

Key Trend

State of the Pathology Profession

no. 5

Internet &amp; Telepathology

20  
02

**D**ON'T FOR A MINUTE THINK that the recent dot.com bust means the end of the revolution in healthcare e-commerce and Internet-based informatics.

Although the failure of many high-profile e-business start-ups, such as **Pets.com** and **WebGrocer** captured the nation's attention and hurt investors' pocketbooks, the unwritten story is that the advance of information-based healthcare services continues at a swift pace.

Even as these high-flying public companies landed in bankruptcy, a number of e-commerce companies demonstrated that the economic model of Internet-based services is viable. **E-Bay** is one example. It provides a place where people can sell anything of value, including junk. E-Bay has effectively altered, even co-opted, the business done by auction houses, pawnshops, flea markets, and garage sales.

E-Bay is the perfect example of how the Internet, and related technologies, can drive down the cost of doing business. That is because the Internet takes costs out of the buy-sell transaction. With minimal cost and effort, sellers can advertise their wares. At equally minimal cost and effort, buyers can locate an item, and compare it for price and quality. Then, both parties can consummate the transaction with great speed.

In healthcare, the move to e-commerce has, for the most part, been more cautious. The boom and bust cycle was concentrated around sites seeking to get consumers (and providers) to pay for access to health information. **WebMD's** physician and consumer portal strategy has so far

failed to gain a profitable foothold in the market. **MedScape** had a similar strategy to provide health information to both providers and consumers. It also failed to grab hold in the marketplace and just last month was sold to **WebMD**. (See page 15.) Then there's the ill-fated **DrKoop.com**, which filed Chapter 7 bankruptcy in the last week of 2001 and exists no more.

Where e-commerce has succeeded in healthcare, it has been on a more modest scale. Some healthcare vendors use the Web to post their product catalogs, take orders, and transact business. Among the best of these is **Fisher Healthcare**, which has earned accolades for the organization and effectiveness of its Web site in this regard.

Within the diagnostics industry, IVD manufacturers are designing their instruments so that on-board systems and reagent usage can be monitored remotely, via the Internet. This will enable them to do preventive maintenance and manage reagent inventories in real time for their lab customers.

Telepathology tracks right along this curve. The cost of effective telepathology systems has fallen dramatically in recent years. Coupled with broadband access, telepathology technology is just about ready for primetime. Look for the federal government, through the **Veterans Administration's** medical system and the military's medical corps, to be among the first to develop viable telepathology services, since it is not constrained by medical licensing laws. An era of huge growth in healthcare e-commerce is almost upon us.



Key Trend

State of the Pathology Profession

no. 6

**Shortage of Paths & Techs**20  
02

**P**OPULAR WISDOM SAYS there is a serious shortage of histotechnologists and cytotechnologists, but that the supply of pathologists is ample, possibly even more than the market needs.

THE DARK REPORT predicts that the pathology profession will be surprised at how fast a shortage of board-certified pathologists develops within the United States. Market forces already underway will fuel a demand for more pathologists.

It will be the opposite phenomenon from the 1990s, when consolidation and pathologist productivity dominated much of the organizational thinking of the pathology profession. During that time, it was recognized that newly-minted pathologists found it difficult to obtain good positions when they finished their medical education.

The real truth about the labor market in pathology won't take long to make itself visible to the entire profession. Increases in the number of new diagnostic technologies and assays will reach geometric proportions. To support both research and clinical use of such technologies will require growing numbers of trained professionals at all levels, from techs to Ph.D.s and M.D.s.

However, the educational system is already turning out insufficient numbers of trained professionals. It will take some time before the resources exist to train larger numbers of people for these jobs. There will be several years of imbalance in the supply of trained technologists and pathologists versus the demand.

Of course, one way to bring supply into line with demand is to

pay more. Thus, compensation for both trained techs and pathologists should increase in the coming years.

In the short term, however, parsimonious Medicare reimbursement for professional services will be an obstacle to attracting more labor through higher wages. But governments cannot subvert the marketplace forever. At some point, rational pricing for pathology and lab testing services has to occur. As it does, labor supply imbalances will be corrected.

There is another factor which will drive the demand for more pathologists. As Robert McGonnagle, Publisher of *CAP Today*, recently observed, "Many pathologists overlook that fact that the increasing complexity of pathology cases is requiring more pathologist time per case. Growing numbers of molecular diagnostic procedures can be used to supplement visual analysis of tissues."

McGonnagle correctly notes that the growing number of AP and molecular procedures which are appropriate for individual cases requires more pathology time per case. Match that fact with the volume increases to come as baby boomers reach their retirement years, and it becomes clear that the existing supply of pathologists will quickly be eclipsed by that increased volume of work.

Not surprisingly, that's one important reason why THE DARK REPORT believes that the pathology profession is soon to enter a Golden Age. The needs of the healthcare community for sophisticated pathology services will be higher than at any time in history.

**TDR**

## Palm Beach Pathology Builds Market Share

# *Histology Lab Goes Mobile To Serve Customers On-Site*

BY JUNE SMART, PH.D.

**I**N SOUTH FLORIDA'S HIGHLY-COMPETITIVE market for anatomic pathology services, **Palm Beach Pathology** has taken customer service to a higher level by offering mobile, "come to your site" histology and pathology services.

To set itself apart from other pathology groups, Palm Beach pathology operates a mobile histology van. "For about ten years, we've used this mobile van to offer clients on-site pathology services," stated Michael J. Imber, M.D., Ph.D. "We've found this service to be particularly popular with ambulatory surgery centers (ASC) and dermatologists."

Palm Beach Pathology is located in the coastal community of West Palm Beach, Florida, about 70 miles north of Miami. It is a 16-pathologist practice, of which two, including Dr. Imber, are dermatopathologists. The anatomic pathology (AP) group serves numerous hospitals, health systems, physician practices, and surgery centers in Palm Beach and Martin County.

"South Florida has always been a competitive market for anatomic pathology services," observed Dr. Imber. "In this region, several pathology groups have aggressively marketed their services. We decided to develop mobile

**CEO SUMMARY:** *During the 1990s, pathologists at Palm Beach Pathology recognized that more and more procedures were being done in ambulatory surgery centers and physicians' offices. To maintain access to these patients, Palm Beach Pathology developed a strategic marketing plan with a unique feature: a mobile laboratory that could process specimens at the clients' site and provide referring doctors with a fast diagnosis. Although the mobile lab is not a profit center by itself, it has helped Palm Beach Pathology build market share and develop new accounts with key providers in its service area.*

pathology services about ten years ago as a way to expand our business and gain market share. We considered AP services, delivered closer to the point of care, would be a competitive advantage with certain types of clients.

### **Mobile Pathology Services**

"At that time, we could identify two mobile pathology services, operated by a pathology group in Orlando and one in Greater Miami," he recalled. "The goal was to provide similar, but better, service to burn centers, hospitals, dermatologists, and plastic surgeons in our service area. By bringing our pathologists closer to the physician during patient procedures, we

would develop bonds that would strengthen both our clinical and business relationships with client physicians.

"Because we already had a strong presence in this market, we also believed it would not take an expensive marketing campaign to introduce mobile pathology services," stated Dr. Imber. "In fact, that's how it worked out. We used a low-key marketing approach and that kept our start-up costs relatively low."

"The next step was to design the actual mobile laboratory," explained Dr. Imber. "One of our pathology group's marketing team was good at design

work, so he took the lead role in developing the mobile pathology van.

"We wanted a safe, efficient and comfortable work environment for two people," he added. "There would be a pathologist and a histotechnologist, along with all the necessary equipment. Of course, the mobile laboratory had to meet federal and state regulatory guidelines.

"We purchased a GMC van. The roof was modified to allow us to stand up inside," he said. "The van was equipped with a cryostat, microtome, generator, sink, hood, air conditioner, microscope, and dictation unit. It is roomy enough that two people can work inside at the same time.

### **Adequate Working Space**

"The mobile lab's design allows us to gross, microtome, stain, cover slip, and read the slides. The aisle space only allows room for one to pass by at a time, but the total space compares favorably to the amount of space some facilities dedicate to frozen specimens," commented Dr. Imber.

Noxious fumes are not an issue, since the only chemicals used in the staining process, including xylene and alcohol, are contained in the staining equipment. In fact, Palm Beach Pathology was able to completely equip the mobile laboratory

## **Mobile Histology Lab Has Adequate Room**

**W**henever the mobile laboratory service offered by Palm Beach Pathology takes to the field, it usually is scheduled for about 50% of a working day. What's it like to do laboratory work in the constricted area of a mobile van?

Michael J. Imber, M.D., Ph.D. and a dermatopathologist at Palm Beach Pathology, is more than six feet tall. He likes the environment. "Working in a GMC van is not as challenging as some may think. For example, the van's roof was modified to allow us to stand up and work. The layout of the van actually makes it a comfortable work environment.

"During client visits, two of us work in the mobile lab at the same time," he continued. "Because of the van's design and layout, we don't get in each other's way. The histotech can efficiently gross, stain, and cover slip while I read slides and do dictation. It's organized to allow us to both be productive while we are on site."

with off-the-shelf items. This further minimized the cost of building the lab.

"Designing and equipping the van was relatively easy compared to operating the mobile lab," Dr. Imber observed. "We've learned that it takes the right kind of histotechnologist to make the concept of the mobile pathology lab work successfully. For example, a histotech needs to be willing to drive the van to the client's site and work in this unique, somewhat re-

stricted, environment. Also, the histotech will have more direct contact with our customers, which is not always the case in the lab."

## **Minimizing Downtime**

Dr. Imber explains that pathologists typically drive their own car to the client site. "This minimizes our downtime, since the histotech can arrive early, prepare the lab, and start processing the specimen in advance of the pathologists' arrival," he explained.

"In regard to regulatory issues, there were no special requirements for our mobile laboratory," recalled Dr. Imber. "It proved to be no different than the standard clinical laboratory. We have the same monitoring and follow-up as if the lab van were in a building. But there are some extra things for which you must be aware.

"For example, when not in use, the mobile van must be parked where it can be hooked up to a continual power supply," he said. "This keeps the cryostat cold, otherwise it won't be ready to go. Also, experience has taught us lessons which we've incorporated into a checklist so we don't overlook anything."

## **Carries a Full Caseload**

A typical day in the life of Palm Beach mobile pathology starts with the organization of the daily surgical workload. A staff member coordinates surgical cases for the "mobile pathologist" of the day. "Each mobile pathologist carries his or her normal caseload for the day," commented Dr. Imber. "It's just done at a different location. While waiting for a frozen section in the mobile lab, I can read slides from the previous day's outpatient surgicals. This minimizes downtime and the daily workload is maintained at a surprisingly optimal pace. Reports are easy. We give the referring physician a verbal report and send the hard copy the next day after routine processing."

There is an unexpected reward from this outside pathology service. Dr. Imber declares that “it puts you in touch with the outside world. Often you go into the physician’s office and meet the nursing staff and the patients. This is very unlike the outpatient laboratory.

“In fact, most physicians enjoy introducing their patients to a pathologist; it makes the patients feel special to think that their specimen will be read during the time they are under the knife,” noted Dr. Imber. “Because of this positive effect on patients, there’s no shortage of plastic surgeons or dermatologists that want to schedule us to take the van to their offices and read their frozen sections.

“However, to maximize the productivity of our pathologists, we carefully monitor the number of cases we handle with the mobile lab,” he added. “Currently we schedule the van about three times a week and usually have 3-4 cases for the morning. This gives us about 50 cases per month.

### **Pathologists In Rotation**

“There are three pathologists who usually operate this service,” continued Dr. Imber. “Two are dermatopathologists and one is a non-skin pathologist. This way we always have a backup and can share the workload. Personally, I enjoy this aspect of my work because it gets me out of the laboratory for half a day, plus the van provides a peaceful and quiet working environment.”

What about the financial performance of the mobile histology service? Does it make money? According to Dr. Imber, the mobile lab was never designed to be a stand-alone profit center. “Our original goal in offering on-site pathology to selected clients was less about generating direct profits from the service, but rather to anchor important account relationships.

“For a smaller pathology practice, I’m not sure if it would be profitable enough for them to use this type of approach,” he offered. “Our mobile lab is one of a full menu of services offered by Palm Beach Pathology. At budget time, we look at the expense of this service as part of a bigger strategic marketing strategy. We don’t expect it to be financially self-sustaining.”

Although not run as a stand-alone profit center, the mobile laboratory does reasonably well on its own and billing arrangements are straightforward. “Revenue from this service is billed exactly like the outpatient laboratory,” observed Dr. Imber.

### **Mobile Lab Backs Up Clients**

The ability to perform on-site pathology leads to some interesting service scenarios. “We also service physicians with offices in close proximity to the surgery centers,” Dr. Imber added. “If one of those physicians conducts minor surgery in their office during the time we are scheduled to be at the nearby surgery center, then one of their staff members brings the specimen to the van and we provide the results almost immediately. Our clients appreciate this type of service. We are a backup for them that’s not available anywhere else.”

As Dr. Imber notes, Palm Beach Pathology’s mobile laboratory provides a variety of added-value benefits to physicians who use its services. But intense competition in South Florida for pathology specimens makes it necessary to continue to innovate. Palm Beach Pathology is preparing to introduce telepathology services as a way to protect and increase its market share.

### **Underserved Regions**

“In central Florida and the Everglades, there are several areas underserved by pathology services,” observed Dr.

Imber. "As an example, there are small hospitals that do not have full time pathologists. These hospitals are excellent candidates for telepathology."

To serve this market, Dr. Imber is developing a mobile telepathology concept. "This is a way to allow a pathologist to remain at the central lab," he said. "The histotech drives to the client, prepares the tissue, places the slide on the microscope, and the pathologist can read the slide using a wireless Web connection.

"As a foundation for this service, we've already introduced digital and video images for some reports from the main lab," Dr. Imber noted. "A consultant is helping us develop the telepathology capability."

## Outpatient Procedures

THE DARK REPORT believes that Palm Beach Pathology's mobile laboratory is a valid response to an ever-growing trend. During the past ten years, there has been a significant shift away from inpatient procedures. The number of outpatient surgery and other procedures has grown significantly. That is reflected in the larger number of ambulatory surgery centers, as well as the growing numbers of physicians performing minor surgical procedures in their offices.

Mobile pathology is a rational way for local pathology groups like Palm Beach Pathology to support outpatient procedures and maintain access to patients which formerly would have been served by the hospital. It is consistent with the need to lower the cost of care while improving the overall quality of care.

THE DARK REPORT notes the experience of Palm Beach Pathology also demonstrates that both physicians and patients respond favorably when given direct access to the pathologist. This is the marketplace speaking to the

pathology profession. It is one sign that pathology groups willing to be more visible within the healthcare community will probably gain a competitive advantage over pathology groups who chose to maintain a lower profile.

## Appropriate For Some Areas

Of course, a mobile pathology lab is not a practical business strategy in many areas of the United States. But it may be appropriate in densely-populated markets where there is increased competition for patients. Examples of such areas are Los Angeles, Houston, Atlanta, and Chicago.

What Palm Beach Pathology has done with its mobile lab is provide an expert, local, and instantaneous pathology result to its most valuable clients. It is using this added-value service to leverage its business relationship and expand its share of the office-based physicians' market.

Because it was willing to invest in this mobile lab as part of an overall marketing strategy to gain share and build specimen volume, Palm Beach Pathology has managed to protect its turf from the inroads of other pathology competitors in the area. That is a significant accomplishment, given the intense competition for specimen referrals from office-based physicians in the South Florida market.

## Willing To Invest Capital

The marketing strategy used by Palm Beach Pathology involved more than offering mobile pathology services. The mobile lab was part of an integrated business plan that required the pathologists to invest capital and management resources to expand the volume of specimens and revenues flowing into their group practice.

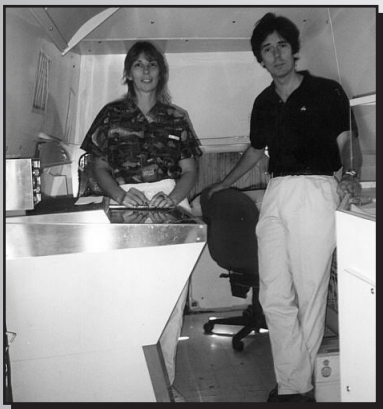
**TDR**

Contact Michael J. Imber, M.D., Ph.D.  
at [imber@pathlab.com](mailto:imber@pathlab.com).

## Palm Beach Pathology's Mobile Lab Speeds TAT at the Client's Site



■ Palm Beach Pathology's mobile laboratory is a converted GMC van. Nightly it is parked outside the main lab so that an electrical hook-up keeps the cryostat cold and ready for immediate use. Standing next to the mobile lab are Michael Imber, M.D., Ph.D. and Doni Daniels, the histotechnologist who most frequently operates the lab.



■ This photo shows the arrangement inside the mobile lab, looking from front toward the rear. The cryostat is visible at left. At the rear is the pathologist's workstation with microscope and dictation equipment. Typically the mobile lab is scheduled for morning procedures and does 5-6 cases at a client's site. As shown, two people can easily work in the organized lab space.



■ This is the view from the rear looking toward the front of the van. It shows how Palm Beach Pathology developed a compact, yet efficient lab space. The sink and staining area is at right, with the driver and passenger seats in the very front of the mobile laboratory.

## Lab Industry Briefs

### ***PACIFICARE BEGINS SERIOUS RESTRUCTURING TO SHIFT EMPHASIS***

NOT SO MANY YEARS AGO, **PacifiCare Health Systems Inc.** was considered the quintessential embodiment of all that was expected to be good with managed healthcare.

The company's business model was studied and copied in cities throughout the country. It shifted 100% of the risk on providers, used capitation almost exclusively, and concentrated on sales, marketing, and administrative responsibilities.

As noted earlier in THE DARK REPORT, this business model collapsed in recent years as hospitals and other providers refused to accept capitated contracts. To stay alive, PacifiCare has begun to develop PPO and POS products. This transition process makes PacifiCare a good bellwether for the larger changes occurring to the managed care industry.

Last week, PacifiCare announced it would lay off 1,300 employees, or about 15% of its staff. For the most part, these people work in the HMO programs, which are being de-emphasized at PacifiCare. The company will take a \$60 million pre-tax charge in fourth quarter to cover severance and related costs.

As part of the company's restructuring, it has announced contracts with **IBM** and **Keane Inc.** to outsource its information technology operating and software maintenance systems. Over 10 years, the two contracts are worth \$1.2 billion.

THE DARK REPORT observes that healthcare is an area where IBM wants to establish a big presence. IBM believes that information management

capabilities will be a source of added value. Moreover, it is expected that molecular and genetic testing will begin generating so much data that providers, including laboratories, will be challenged to both archive the data and then mine it for useful information. For that reason, IBM's contract with PacifiCare should be seen as part of its larger business strategy to become a major player in the healthcare informatics marketplace.

### ***MEDSCAPE SELLS ITS INTERNET PORTAL BUSINESS TO WEBMD***

EVEN AS **DRKOOB.COM** WAS FILING Chapter 7 bankruptcy in December, **MedicaLogic/MedScape Inc.** was selling its two healthcare Internet portal businesses to **WebMD**.

In a deal valued at \$10 million, WebMD acquired *medscape.com* and *medscapehealth.com*. These were Internet portals for healthcare professionals and consumers, respectively. MedicaLogic/MedScape will concentrate on its digital health records business. (See *TDR*, November 26, 2001.) It will conduct business under the name of MedicaLogic.

The failure of MedScape and DrKoop.com to make money as healthcare information portals is probably due to the huge volume of free health information available from many credible sources on the Internet.

Laboratory administrators and pathologists should track the progress of MedicaLogic in selling its software solutions for clinical decision support and digital health record management. Both products touch upon laboratory test ordering, results reporting, and archiving lab test data.

# Patent Access Limits Rapid HIV Testing in USA

*Companies developing rapid HIV tests for U.S. are unable to obtain rights to use HIV-2 virus*

**CEO SUMMARY:** *Diagnostic manufacturers will begin to face the same controversy over public access to diagnostic testing technology that has dogged pharmaceutical companies in recent years. Public health officials and the military are unhappy with how Bio-Rad and its HIV-2 licensees have failed to provide the United States with a rapid HIV-2 test.*

**E**XPECT MORE CONTROVERSY over biotechnology patents which limit access to technology that can be used in diagnostic testing. These patents grant a 17-year monopoly on the commercial use of genes, viruses, organisms, and scientific processes.

The latest case to receive public attention is **Bio-Rad Laboratories Inc.**'s patent covering the HIV-2 virus. On December 20, 2001, *The Wall Street Journal* ran a front page story about the role this biotechnology patent has played in hindering development of a "rapid" HIV test in the United States.

## **Fast, Accurate And Cheap**

Rapid HIV tests use a drop of blood or saliva as a specimen and can provide acceptably accurate results in just minutes without the need for sophisticated equipment. Several vendors provide rapid HIV tests that are widely-used in Europe and many undeveloped countries. But despite the proven effectiveness of this point-of-care testing method, there are no rapid HIV tests available in the United States.

This contradiction was the subject of the *WSJ* story. Bio-Rad gained the patent to the HIV-2 virus when it acquired **Sanofi Diagnostics Pasteur** in 1999. Through the 1990s, Sanofi and then Bio-Rad had granted licensing rights to the HIV-2 virus to **Abbott Laboratories**, **Chiron**, and **Johnson and Johnson's Ortho-Clinical Diagnostics** (OCD) division.

These companies developed HIV testing kits which run on their sophisticated instrument systems and must be done in licensed laboratories. In the United States, the HIV testing market is about \$200 million per year.

The public interest issue involving access to the HIV-2 patent has also developed during the 1990s. HIV-2 is a strain involved in about 25% of HIV infections in West Africa. In the United States, only about 200 cases of HIV-2 have been reported. But the numbers of such cases are increasing in New York City and Washington, DC, both cities where there are sizeable communities of West African immigrants.



Advocates of rapid HIV testing are public health officials and the military. Public health officials note that up to one-third of the individuals who show up at public clinics and get an HIV test do not come back for their results. A rapid HIV test, requiring only minutes to generate reliable results, would be a boon in their efforts to control the disease and treat infected individuals.

### Unscreened Transfusions

For the military, the issue is how to prevent accidental transmission of HIV-infected blood on the battlefield. After the explosion on the U.S.S. Cole, for instance, stockpiled blood ran out and injured sailors were transfused with blood from those at the scene. That blood was unscreened for HIV, since the Navy lacked an FDA-approved rapid HIV test.

So why does the United States lack the same rapid HIV tests used to such great effect worldwide? This time the “villain” is not the FDA. It’s the diagnostics vendors with licenses to the HIV-2 virus. The licensing agreements between Bio-Rad, Abbott, Chiron, and OCD require that all licensees approve the extension of licensing rights to additional companies.

To date, companies like **Universal Healthwatch**, **OraSure Technologies** (formerly **Epitope**), **MedMira Laboratories**, **Chembio Diagnostic Systems**, and **Trinity** have all developed effective rapid HIV tests. But Bio-Rad has refused to grant licensing rights to the HIV-2 virus. This prevents these firms from gaining FDA approval and distributing rapid HIV test kits in the United States.

### CDC’s Frustration

Officials at the **Centers for Disease Control (CDC)** and within the military are very frustrated at this situation. *The Wall Street Journal* published

the following strong comments. “They have, [Bio-Rad, Abbott, Chiron, OCD] locked everyone out of the U.S. market,” says Nelson Michael, chief of molecular diagnostics at the **Walter Reed Army Institute of Research**, the U.S. military’s medical-research center. Bernard Branson, the CDC’s epidemiologist in charge of HIV diagnostics, says, “I’d call it restraint of trade. It’s a travesty to stand by and allow these tests to languish.”

THE DARK REPORT believes the WSJ’s front page article was triggered by frustrated officials within the public health sector and the military. This debate is typical of others to come. It will be “public interest” versus “private incentives” that patents are supposed to encourage.

Within the clinical laboratory industry, PCR technology was an early example of patent access issues and licensing fees that accompany a useful biotechnology patent. However, Roche has been willing to extensively license use of its PCR technology, to encourage its wider use in laboratory and other applications. This has generated substantial licensing fees for Roche.

### Protecting Their Market

In the case of the HIV-2 patent, there are strong arguments that Bio-Rad, Abbott, Chiron, and OCD have collectively preferred to deny licensing rights to companies developing rapid HIV kits, which are commonly sold worldwide for about \$2 each. This protects their market in the United States, which is built upon more expensive kits which are run on complex instrument systems.

Adding fuel to that fire is the fact that Bio-Rad, Abbott, and OCD have made easy-to-use rapid HIV test kits for sale overseas, but have not introduced them into the United States. **TDR**

# INTELLIGENCE

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



Here's an early conjunction of:

1) consumer demand for sophisticated health-care services; 2) healthcare e-commerce, and 3) telemedicine. In Cleveland and Boston, major health systems have introduced a Web-based "second opinions" service. In the case of the **Cleveland Clinic Foundation**, patients can log on and learn how to go about getting a second opinion. If the patient decides to go forward, secure Web sites guide the patient through the process, including how to get the necessary medical history and diagnostic records to the Cleveland Clinic.

## **MORE ON: SECOND OPINIONS**

At **Partners HealthCare** in Boston, the Web site is called "Partners Online Specialty Consultations." Patients register on a secure Web site and print a letter which they take to their primary physician, who then initiates contact with Partners. Pathologists should take note: By the end of 2001, 250 patients had registered, with most wanting second opinions involving oncology.

## **ROBERT PETRAS, M.D. WILL AFFILIATE WITH AMERIPATH**

It's an example of both pathology branding and how national pathology centers of excellence will be developed. **AmeriPath, Inc.** announced on January 3, 2002 that Robert E. Petras, M.D. had joined the AmeriPath team as of January 1. Dr. Petras was most recently Chairman, Department of Pathology at the **Cleveland Clinic**. A noted expert in gastrointestinal pathology, Dr. Petras' arrival at AmeriPath will enhance the company's credibility in this pathology subspecialty.

## **ADD TO: PATH BRANDING**

Perceptive readers of THE DARK REPORT will recall the other "marquee" pathologist affiliated with AmeriPath. Dermatopathologist A. Bernard Ackerman, M.D. joined the company in July 1999 when it announced the formation of the **Ackerman Academy of Dermatopathology**, to be located in New York City. As predicted on these pages, pathologists of recognized clinical expertise will increasingly be recruited into pathology companies

seeking to develop centers of excellence that, because of recognized clinical expertise, can draw case referrals from a national and international marketplace.

## **COMINGS & GOINGS:**

- In Manchester, New Hampshire, the 630-bed **Catholic Medical Center** has decided to transfer its outreach laboratory subsidiary, **New Hampshire Medical Laboratories (NHML)**, to **Pathlab, Inc.** of Portsmouth, New Hampshire. The transition is underway and should be completed in February. NHML operated for 14 years. PathLab is owned and operated by **Laboratory Corporation of America**.

- Privately-owned **BC BioMedical Laboratories** of Vancouver, British Columbia was recently recognized by the *Toronto Globe & Mail* as one of Canada's "Top 50 Best Companies To Work For In Canada." It placed number six on the list. Congratulations to Managing Director Douglas B. Buchanan and his management team!

***That's all the insider intelligence for this report.  
Look for the next briefing on Monday, January 28, 2002.***

## *PREVIEW #3*

### **EXECUTIVE WAR COLLEGE**

May 7-8, 2002 • Astor Crowne Plaza • New Orleans

#### **Topic: Threats and Profit Opportunities In Molecular And Genetic Diagnostic Testing**

There's plenty of opportunities in molecular and genetic testing for hospital labs—but only if they balance the risk with the reward. Learn from the early adopters how to establish a profitable molecular testing program, one that makes money even as it provides clinicians with state-of-the-art testing they need and want in their practice.

**Full program details available soon—call 800.560.6363  
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## ***UPCOMING...***

- ***THE DARK REPORT Digs Behind the Shortage of Trained Lab Techs: Who's Hiring Them Away From Clinical Labs?***
- ***Using Workstation Consolidation to Boost Productivity and Slash Average-Cost-Per Test in Big and Small Hospital Labs.***
- ***Managed Care's New Threat To Laboratories: How Contracting Practices Are Evolving.***

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