

From the Desk of R. Lewis Dark...

THE **RD**ARK **REPORT**

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

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R. Lewis Dark

Founder & Publisher



Making a Difference in Tangible Ways

HOW OFTEN DOES SOMETHING you learn from THE DARK REPORT make a positive difference in your laboratory? We hear lots of examples from our clients and regular readers and I'd like to share two of them with you today.

The first example comes from our special, exclusive, and expanded coverage about anatomic pathology (AP) condominium laboratory complexes. This exploding trend involves specialist-physicians taking active steps to bring AP revenues into their medical practice. (*See TDRs, July 19 and August 9, 2004.*) Among the topics covered by THE DARK REPORT were potential legal and compliance concerns triggered by an AP condo lab operation, the nation's first look at widespread utilization rates for a 12-core prostate biopsy procedure, and public concerns already expressed by a Senator and the **Office of the Investigator General (OIG)** about the legitimacy of the AP lab condo business scheme.

The message seems to have gotten out. Pathologists in recent weeks tell THE DARK REPORT that many urology and gastroenterology groups in Florida have suddenly lost interest in acquiring their own AP laboratory condominium. From another reliable source comes word that an original investor in one of the companies that operates and promotes AP laboratory condos asked the company to go to outside to a first-rank law firm for an objective legal opinion on this business scheme.

My second example is equally fascinating. Remember the **Maryland General Hospital (MGH)** laboratory case last spring? That is the hospital lab which, for 18 months, released unreliable HIV and HVC test results, and then, only after whistleblowers finally caught the attention of Maryland laboratory regulators, was determined to be operationally deficient in a variety of ways. (*See TDRs April 5, April 26, and May 17, 2004.*) The laboratory director during this time, James Stewart left MGH under a cloud. However, he then found employment with one of the two blood brothers in New Hampshire, apparently working in a hospital lab. Pathologists involved with that hospital recognized his name from reading THE DARK REPORT. They contacted his employer and expressed concerns about his competency for that position. To its credit, that lab company swiftly terminated Stewart.

Both examples show how THE DARK REPORT makes an important difference in tangible ways. I'd love to hear such stories from all of you. **TDR**

Is Nation's Best Quality Laboratory in Arizona?

Sonora Quest Laboratories wins one award, sets sights on Arizona's highest quality prize

CEO SUMMARY: *Without much fanfare or public attention, one lab is achieving recognition for quality and service excellence possibly unmatched in the clinical laboratory industry. In 2003, Sonora Quest Laboratories received Arizona's Pioneer Award for Quality—the first healthcare provider in Arizona to win that award. Its next goal is to achieve the state's highest honor, the "Governor's Award for Quality."*

QUALITY MANAGEMENT METHODS are gaining rapid acceptance within the clinical laboratory industry. One laboratory leading this trend is **Sonora Quest Laboratories (SQL)** of Tempe, Arizona. It may possibly be the nation's highest quality clinical laboratory.

It has credibility to make this claim. In 2003, Sonora Quest Laboratories was awarded the "Pioneer Award" through the State of Arizona Quality Awards program. SQL was the only company in Arizona to be so recognized in 2003. It was recognition of SQL's commitment to continuous improvement and its effective deployment of quality management systems throughout its operations. The Arizona quality awards are based on Baldrige Award criteria.

Sonora Quest Laboratories (SQL) is a joint venture LLC between **Banner Health**, Arizona's largest healthcare system, and **Quest Diagnostics Incorporated**, the nation's largest clinical testing provider. SQL is also part of an integrated laboratory network that includes **Laboratory Sciences of Arizona LLC (LSA)**, which manages the six hospital laboratories for Banner Health.

What makes SQL's accomplishment more notable is that Sonora Quest Labs is the first healthcare provider in Arizona to win that award. Not content to rest on these laurels, Sonora Quest Labs is pursuing a more ambitious goal.

"Our entire laboratory organization is actively working to achieve the Ari-

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zona Quality Program's 'Governor's Award' in 2005," stated David A. Dexter, CEO at Sonora Quest. "It's the highest level of achievement within Arizona's quality awards program."

The significance of Sonora Quest Laboratories' Pioneer Award extends beyond the accomplishment it recognizes. It is one of those marketplace events which raises the competitive bar in laboratory management. SQL has developed an organizational culture and employee mindset that directly contributes to higher levels of service and customer satisfaction. It is continuous improvement in action.

Managing To Objective Data

That statement can be supported by objective data. "We measure everything," said Dexter. "If you don't measure it, you can't manage it. We know how our customers view us because we measure their satisfaction with our services. We also measure how the market judges the quality of our competitors' lab testing services. That data tells us we are doing very well, both against our own past performance and against the performance of our competitors."

A site visit to Sonora Quest Laboratories provides first-hand evidence that Deming-based principles of quality management can deliver higher quality laboratory testing services, at a lower cost, over a sustained period of time. It demonstrates how continuous improvement delivers ongoing benefits.

"Every laboratory understands the importance of delivering an accurate test result in a timely fashion," observed Dexter. "We have a moral and ethical obligation to deliver error-free services. Four years ago, there were significant operational and financial issues in almost every area of our business. SQL was not competitive in many ways. With great support from Quest Diagnostics, we launched our

Six Sigma program as a process improvement methodology to fundamentally reinvent our laboratory operations and to develop Quality as a major competitive edge and as a point of differentiation in the marketplace.

Measurements As A Guide

"Six Sigma provided every person in this laboratory with a goal. It gave us direction and focus. As we made our initial measurements of performance in different areas of the lab, we could then quantify the existing state and begin improving it. Our objective is to perform at the 'world class' level," he explained.

There are several noteworthy attributes within SQL which set its management culture apart from that commonly found in other laboratories. First, it develops a business plan yearly that drives the entire business. "The planning process starts with the executive leadership team identifying relevant goals for the upcoming year," Dexter said. "At this stage, the business plan outline and basic goals are passed down the management ladder. It reaches the supervisor level and is shared with all employees.

Strategic Business Plan

"Our supervisors and managers are asked to contribute to the plan by identifying how they will achieve these goals and the resources they will need," he continued. "The plan works its way back up the management ladder. At each stage, it is refined.

"By the end of this process, the entire integrated laboratory organization is aligned behind the upcoming year's business goals and has an identified and feasible plan to achieve those goals. Execution of the plan is vital to success, and we have a high-performance management team that delivers the expected results," he said.



**Sonora Quest
Laboratories**
www.sonoraquest.com

At-A-Glance

Sonora Quest Laboratories: Commitment to Quality Systems

- JV Formed:**.....1997
- JV Partners:**.....Banner Health, Quest Diagnostics Incorporated
- Main Laboratory:**.....120,000 sq. ft. laboratory in Tempe, AZ
- Daily Tests:**.....40,000
- Integrated Lab FTEs:**.....1,200 for SQL and 600 for the hospital laboratories.
- Patient Service Centers**.....54
- Clients:**.....5,000
- Management Team:**.....
 - Chief Executive Officer:** David A. Dexter
 - Chief Operating Officer:** Joyce Santis
 - Chief Financial Officer:** Jennifer Andrew
 - Chief Information Officer:** Bob Dowd
 - VP, Sales & Marketing:** Joe Serfaty
 - Executive Director of Quality:** Jean Hammelev
 - Executive Director, Human Resources:** Byron Farwell
 - Executive Director, Compliance:** Kim Fleurquin
 - Executive Director, Hospital Operations:** Barbara Blasutta
 - Medical Director:** Kent Zimmerman, M.D.

Sonora Quest Laboratories is a joint venture between Banner Health and Quest Diagnostics Incorporated. Its testing services are integrated with Banner’s hospital laboratories and the outreach marketplace. Below are some outcomes from its quality management initiatives.

Six Sigma Project Results

STAT Emergency Department Lab TAT:

- 61% reduction—order to specimen collection cycle time.
- >50% reduction—specimen receipt to verified results cycle time.

Specimen Misidentification:

- 59% reduction in mislabeling errors.

Phlebotomy Safety:

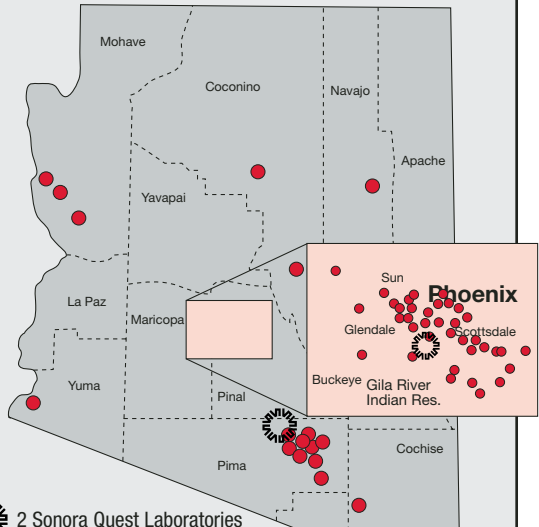
- 70% reduction in needle sticks.

Specimen Management:

- 90% reduction in specimen management data entry error rates.

Customer Service:

- 67% reduction in billing customer service speed of answer.



2 Sonora Quest Laboratories



54 Patient Service Centers

A second distinctive attribute is that all employees of SQL participate in an incentive plan linked to achievement of each year's goals. "Management here works earnestly to align the motives of everyone connected with the laboratory," observed Dexter. "The best description of our business plan is that it is a road map. It guides everyone toward the goals and keeps us aligned throughout the year."

There is no magic management bullet which transformed Sonora Quest Labs. "Any quality management system like Six Sigma is tough to implement," offered Dexter. "Every individual working in the laboratory, from entry-level to CEO, has to learn new ways to conduct business, to measure outcomes, to improve work processes, and to relate to customers. The easy path is to go back to the 'old ways.' The tough path is to stay with it until these management methods and techniques are mastered."

Benchmarking The Best

A third unique attribute is the intense measurement of all work processes and outcomes. SQL regularly uses outside specialists to conduct surveys and measure services. "We want to know what 'best practice' and 'world class' is for every function and service in our laboratory," said Dexter. "In addition, SQL is able to benchmark metrics with Quest Diagnostics business units. Also, the LSA managed hospital laboratories are all benchmarked nationally for key metrics, with similar hospital laboratories, according to size and degree of acuity.

"For example, we pick up and deliver packages, just like **Federal Express** and **UPS**. We maintain a customer service department, just like the major credit card companies. Outside experts help us learn what they do which makes them 'world class' in

these functions, so we can improve to that level ourselves," he explained.

A fourth attribute is the full-time staff SQL maintains to support its quality management programs. "Six full-time employees are dedicated to quality," stated Jean Hammelev, Executive Director of Quality. "We know there is payback from this investment because we measure the gains they produce.

"As measured by outside experts, our customer satisfaction scores show sustained improvement each year."

"Over the four years of our Six Sigma journey," continued Hammelev, "more than 50 people within SQL have earned their Green Belt designation. We are actively doing 'champion' training for 100% of our managers and supervisors. This shows how the learning process grows outward, encompassing ever greater numbers of people in our laboratory."

The educational process within Sonora Quest Laboratories is reinforced by a requirement that 100% of staff members undergo training annually in areas of quality, customer satisfaction, safety, and compliance. Anything short of 100% compliance with this training impacts a portion of all employees' incentive payout.

Employee Satisfaction

Do the employees of SQL like their work environment and like using Quality management methods to improve processes? "The answer is yes! We know this because we measure it," said Hammelev. "We have 1,800 employees throughout our integrated systems and 98.8% of them complete our employee satisfaction

survey. We've also experienced a significant decline in employee turnover. Several years ago, the voluntary turnover rate among laboratory employees was 36% per year. That's now fallen to about 11%."

"You can't have a quality laboratory operation if you don't retain and continually train your employees in quality and customer service," added Dexter

Dexter pointed out that employees are supportive for another reason. "We read their satisfaction surveys and they know we act upon their requests and suggestions," he said. "The **Gelfond Group** measures us in this area. SQL has achieved 'world class' in the past two years for employee satisfaction. The Gelfond Group told the Board of Directors of Sonora Quest Laboratories that SQL achieved world Class employee satisfaction in two years—faster than any company in the history of their 25,000 company database! We are very proud of this accomplishment."

Benchmarking The Best

The most important unique attribute has been saved for last. That is customer satisfaction. "Our entire laboratory is organized around the 'Voice of the Customer'," declared Dexter. "Voice of the Customer is incorporated into each Six Sigma project we do. We strive to be error-free, on time, every time. Our Customer Satisfaction Index has improved significantly and we are now approaching world class."

"As measured by outside experts, our customer satisfaction scores show sustained improvement each year," said Joyce Santis, COO at Sonora Quest Laboratories. "Because our Six Sigma projects are driven by the Voice of the Customer, improvements they generate are noticed by customers. This shows up in the customer satisfaction surveys and by unsolicited comments they make to our sales reps and client services staff."

"There is another important group of customers that knows about our continuous quality improvement. It is the payers. They no longer say that laboratory testing is a commodity," commented Dexter. "We worked hard to change that attitude. We have the data to prove it. We meet quarterly with each of our payers and show them the metrics that document our performance and our improvement from earlier months."

Benchmarking The Best

THE DARK REPORT offers Sonora Quest Laboratories as a unique example within the laboratory industry. It is an early-adopter lab that has pushed the quality management principles articulated by W. Edwards Deming farther into its organization than any other laboratory known to THE DARK REPORT.

There are many invaluable lessons in laboratory management to be learned from the experience of Sonora Quest Laboratories. It is employee-friendly. Once lab employees understand how the new management philosophy uses hard data to drive decisions and improvements to the work flow, they become more supportive.

It is customer-friendly. By surveying customer expectations and focusing operational improvements on issues that matter to customers, the lab's service quality improves. Customers notice these changes. In the case of Sonora Quest Labs, client physicians and payers also recognized these improvements.

Most importantly, the disciplined implementation of quality management systems into this laboratory has supported strong revenue growth and profitability. This financial strength allows the lab to pay performance-based incentives and invest in the resources it needs to remain competitive.

TDR

Contact Dave Dexter, Joyce Santis, and Jean Hammelev at 602-685-5000.

Managed Care Update

Double-Digit Increase Predicted For HMO Premiums in 2005

Sixth consecutive year of HMO double-digit price rise will push employers and payers to squeeze labs

THERE'S GOOD NEWS AND BAD NEWS from the 13th annual **Milliman** survey of HMOs. Milliman predicts that the rate of health premium increases will decline by 3.8% over last year's survey. However, the average premium increase for 2005 is still predicted to be in double digits, at 11%.

For the lab industry, this is definitely bad news. It means that both employers and payers will be pushing hard throughout 2005 for hospitals and providers to accept lower reimbursement. All providers will want to anticipate these demands at contract renewal time. THE DARK REPORT recommends that lab directors and pathologists should negotiate with payers from a well-prepared and well-documented position.

Milliman, based in Seattle, Washington, is a respected consulting firm. Its annual survey of HMOs and PPOs is unique because payers "are asked to respond to a given set of benefits and demographics. The survey removes three important factors that can skew the results of a typical survey on health costs: differences in benefit design scope, cost sharing levels, and member demographics."

Milliman's full survey will be released later this fall. It released preliminary results from the first 30% of payers surveyed. For HMOs, the 2005 rate increase is predicted to be 11.0%, compared to 14.8% for 2004. Milliman notes

that this will be the sixth consecutive year of double-digit increases in HMO premiums. For PPOs, Milliman's preliminary findings predict a 2005 renewal rate increase of 12.0%.

These numbers are consistent with findings announced recently by the **Kaiser Family Foundation and Health Research and Educational Trust**, based in Oakland, California. In a survey of 3,000 employers, Kaiser researchers determined that healthcare premiums increased 11.2% during 2004. This reflects an average for various types of payers and a range of insurance plan options.

PPO Costs Climbing

Kaiser's survey determined that the average family premium for a PPO now costs in excess of \$10,000 per year. This is a key statistic, because this number is close to the average annual earnings of a full-time, minimum wage worker.

The implications of this fact are significant for the entire medical profession. Increases in the cost of healthcare insurance are outstripping the ability of employers to fund their employees' health benefits. Significant increases in the number of employed individuals who lack adequate health insurance will trigger an intense political debate. Labs should carefully follow how employers respond to this situation. Their wishes will carry the substantial political clout.

IVD Firms Developing New Marketing Channels

Lab industry vendors want to find more effective ways to reach customers

CEO SUMMARY: *Manufacturers across the IVD industry are aggressively seeking new marketing channels to reach their laboratory customers in more productive ways. That means moving outside the traditional emphasis on the exhibit halls of laboratory professional association meetings. In the case of Abbott Laboratories' Architour, it is a huge semi-tractor trailer rig that brings its newest product right to the lab's doorstep.*

E VOLUTION WITHIN THE LABORATORY TESTING MARKETPLACE IS causing the nation's major IVD (*in vitro* diagnostics) manufacturers to rethink how they market and sell their new products.

Many lab managers and pathologists have observed one visible sign of this trend. In recent years, several of the larger IVD companies revamped their presence in the exhibit halls that are part of the annual meetings of the major laboratory professional associations. Other IVD vendors are squeezing dollars out of their exhibit hall budgets.

Another Sign Of Change

Another visible sign of the change in IVD sales and marketing practices is the appearance of the semi-tractor truck which **Abbott Laboratories** is using to promote its newest instrument system. Starting last April, this big rig began a national circuit designed to bring this new product literally to the front door of laboratory customers.

It only took a couple of months before the success of this marketing

channel encouraged Abbott to build a second big rig and, in July, put it on the national circuit as well.

THE DARK REPORT believes the different ways that IVD companies now use lab industry exhibit halls, combined with the arrival of Abbott's diesel big rig as a "traveling trade show exhibit," reflect deeper, more fundamental changes occurring within the IVD industry. These changes will steadily transform the way IVD vendors introduce their new products into the laboratory marketplace.

Curious about this phenomenon, THE DARK REPORT made a point to show up when the Abbott big rig, dubbed "Architour", arrived in Austin, Texas recently. Certainly most of the major IVD vendors have, at one time or another, put demonstration vans on the road. But the size and scale of this demonstration "van" attracts attention. It also allows Abbott to interact with laboratory customers in ways which go beyond the capabilities of demonstration vans, which contain less display space.

Architour — Vital Stats

Width, extended: 15 feet

Interior space, extended: 650 s.f.

Length: 78 feet

Weight: 68,900 pounds

Height: 14 feet

**Estimated miles traveled
thru 9/1/04:** 32,000



Abbott was willing to share the sales and marketing strategies which led to its decision to build two expensive demonstration trucks and keep them on the road for many months. “The seed of this marketing strategy is a new product which we felt was particularly special,” said Sherri Hopson, Abbott’s Vice President, U.S. Commercial Operations.

“The Architour is specifically designed to showcase our Architect *ci8200* instrument system,” she continued. “It is an integrated chemistry-immunochemistry system and is the first truly integrated product in this category. We believe its capabilities and features represent substantial improvements over existing systems.”

Unique Marketing Channel

“This is where our marketing strategy begins,” added Suzanne Macaitis, Global Marketing Manager. “We wanted to give this new product maximum exposure. Our challenge was to find a different marketing channel to expose this unique product to as many laboratory customers as possible.

“Our first marketing premise was that it is not easy for many lab people to travel to industry meetings. We’ve observed how travel budgets—and travel opportunities—have declined for most laboratory managers,” she continued. “That means it is more difficult to get them to the exhibit hall, whether it’s a national meeting or a regional meeting. For government laboratories, travel is extremely difficult and, in some cases, travel is not allowed. With

Architour, we wanted to be able to complement our other industry activities.”

“It quickly became apparent to us that the best way to reach a huge audience was to bring the instrument directly to their laboratory,” noted Hopson. “Because this is a large instrument system and we wanted to present a live demonstration of its full capabilities, we recognized that a full-size semi-tractor trailer would be needed to do the job. The size of the trailer also allows us to handle the maximum number of people per stop and per demonstration.”

During THE DARK REPORT’s visit to the Architour truck, several benefits to Abbott’s marketing strategy became obvious. First, the truck itself is set up in the parking lot of a hospital. It is within walking distance for lab folks working in that hospital. Also, because many cities often have clusters of hospitals in one neighborhood, it is frequently a short walk or drive for lab personnel coming from nearby hospitals.

More Lab Staff Involved

Second, the composition of the crowd definitely includes all levels of staff and management from nearby hospital laboratories. “This is an interesting dimension to our strategy,” noted Macaitis. “Often med techs who actually run the instrument first see it only when it arrives on site for set-up and training. The live demonstration allows them to see the instrument and interact with it. Hospital administrators, including CFOs, also show up and learn about the instrument.”

From the IVD vendor’s perspective, the Architour truck event helps develop relationships with the company’s regional sales, service, and technical support staff. “This is a great benefit for us,” offered Hopson. “Prior to the Architour’s arrival in town, our sales staff visits the laboratories to meet with people planning to attend a demonstration. This allows the sales staff to identify the unique needs of that laboratory and insure that the demonstration they see is tailored to those specific needs.

“At the time of the demonstration, our regional sales, customer service, and technical support staff do the presentation,” said Hopson. “Lab customers get to know the entire local team that supports this product. This is something we cannot do at the national trade shows.”

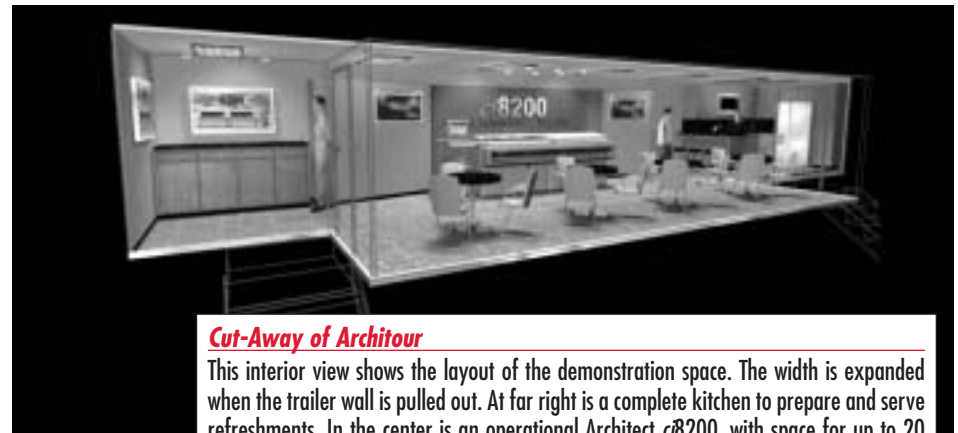
“Also, because the demonstration includes more people from their lab than

would be at an exhibit hall booth, question and answer sessions can be more focused and detailed,” observed Macaitis. “The greater number of participants from the lab gives them the opportunity to review relevant issues in greater depth. That is also something that cannot happen during a national trade show exhibit.”

Marketing With The Internet

Abbott’s decision to literally bring an operational instrument to the doorstep of laboratories around the United States is only one aspect of the changes occurring to the sales and marketing of IVD instruments, reagents, and laboratory products. Abbott is also using the Internet to supplement and support the activities of its Architour trucks.

“Everyone recognizes that the Internet is a new marketing channel,” observed Hopson. “We are using it to



Cut-Away of Architour

This interior view shows the layout of the demonstration space. The width is expanded when the trailer wall is pulled out. At far right is a complete kitchen to prepare and serve refreshments. In the center is an operational Architect *ci8200*, with space for up to 20 people to hear a presentation. At left is a smaller conference area.

Why IVD Marketing/Sales Is Undergoing Change

DURING THE 1990s, consolidation within the IVD industry was just as significant as consolidation within the clinical laboratory industry. Such consolidation had two major effects on the sales and marketing strategies of the IVD industry.

First, it created a new class of “super-big” laboratory customers. Among private commercial labs, regional, pathologist-owned labs were absorbed into larger commercial lab companies, particularly **Quest Diagnostics Incorporated** and **Laboratory Corporation of America**.

Within the hospital laboratory sector, consolidation of hospital ownership created 600+ integrated delivery networks (IDNs). Each IDN wanted to standardize its laboratory services and use exclusive purchase contracts to lower the prices it paid for instrument systems and reagents.

The second consequence of consolidation was that, within the IVD industry itself, the line-up of competitors had changed in important ways. Many IVD acquisitions were done as a way for the acquiring company to broaden its product line. There was a belief that the biggest lab buyers would prefer to buy chemistry, hematology, immunology, and other major instrument systems from a single source.

Now, almost halfway into the decade of the 2000s, there is evidence that the “one source” IVD vendor strategy—the concept that a single IVD manufacturer needs to provide almost 100% of the instrument systems used in a high-volume core laboratory—has not changed the primary buying strategies of the nation’s largest laboratory customers.

However, consolidation within the IVD industry and within the clinical lab industry has had an impact. It changed, in fundamental ways, the sales and marketing strategies of IVD vendors. It also changed the way laboratory customers evaluate and negotiate the purchase of new instruments.

supplement Architour activities in three ways: by e-learning, by e-mail, and by e-conferences.”

“Additionally, customers are offered the opportunity to participate in ongoing learning seminars covering a variety of topics that have CEU credits,” explained Macaitis. “The numbers are becoming sizeable. Last month more than 2,000 people logged on to our e-learning session.”

Has the Architour truck strategy succeeded in attracting laboratory customers to a demonstration? “We think so,” responded Hopson. “Through the end of August, more than 2,400 laboratory customers had seen the demonstration. Our prediction is that, by year’s end, the number will exceed 7,800.”

Marketing Strategy

These are impressive numbers, given the relatively small number of laboratory organizations within the United States. It shows that this marketing strategy has accomplished one of its major goals: getting a new product in front of potential buyers. It has done this by going outside traditional marketing channels.

Laboratory managers and pathologists should watch how IVD manufacturers continue to develop new marketing and sales channels for their products that complement national lab trade shows. The fact that laboratory administrators and pathologists have less time to travel—and don’t have the budget to pay for travel—may make these trade shows less important in future years.

THE DARK REPORT finds it notable that one outcome of this particular marketing strategy is that it got multiple levels of hospital and lab decision-makers and med techs into a demonstration at one time. This is an attribute of the “Information Age”, where customers have access to more and better information before they buy a product. **TDR**

Contact Sherri Hopson at 847-935-4644 and Suzanne Macaitis at 847-936-3323.

How Local Path Groups Can Keep Patient Access

Efforts to restrict non-contract lab providers are increasing in Northeastern states

CEO SUMMARY: *For pathology groups operating their own histology and cytology labs, a growing problem is access to patients covered by exclusive managed care contracts. In the Northeast, several persistent pathology group practices are using some effective business strategies to fight this trend. Not every strategy works every time, but there are enough victories to make the effort worthwhile.*

By Albert L. Giles

Editor's Note: Albert L. Giles is President of Anodyne Green, a pathology consultant and group administrator based in Voorhees, New Jersey. For three decades, Giles has provided business and operational support for pathology group practices primarily in the states of New Jersey, New York, Pennsylvania, Delaware, Florida and California.

PATHOLOGY GROUP PRACTICES which operate their own histology and cytology laboratories are faced with a growing problem: maintaining their access to specimens in situations where they do not hold managed care contracts.

There is a breakdown in the familiar business arrangement between these local pathology group practices and the commercial laboratories that hold managed care contracts. For almost two decades, it was common for commercial lab companies to negotiate "all-in-one" contracts with managed care plans, keep the clinical lab

testing for themselves, and subcontract the anatomic pathology (AP) and cytology specimens to local pathology groups.

These subcontracting arrangements are now a dying breed. In recent years, commercial laboratories have taken aggressive steps to disrupt longstanding subcontracting relationships and capture the AP and cytology specimens for themselves.

Capturing AP Specimens

As the national and regional labs which hold these contracts hire their own pathologists and create the capacity to do the work, they take two steps in the marketplace. First, they terminate their subcontracting relationship with local pathologists and direct those specimens to their own labs and pathologists.

Second, in cases where local pathologists maintain business relationships with physicians in the area, national and regional laboratories collaborate with the managed care companies to enforce the exclusivity clause of their "all-in-one" lab testing

contract. Physicians come under direct pressure to stop referring specimens to the local pathology group.

To counter this trend and preserve access to specimens, my more progressive pathology group clients developed several strategies. None are effective all the time. But each has a time and a place when it can make the difference and preserve access to the AP and cytology specimens needed to sustain local histology and cytology laboratories.

Strategy One

LOOK TO YOUR PPO

If local pathologists participated in the formation of a Physician Preferred Organization (PPO), whether it be hospital-based, multi-specialty, or single specialty, we believe this is the first opportunity to re-visit.

If the PPO protected your pathology group, negotiated for you, and got you fees only for inpatient work, they did not fulfill their responsibility to you. If a pathology group owns a separate lab, or if it is paying technical component to its hospital(s) and marketing outside the hospital, the pathology group has a right to provide services to the PPO's beneficiaries.

In many instances, the pathology group has the right to approach the PPO and reopen the entire issue. It can force the PPO to renegotiate contracts with the "universal" laboratory provider so that lab company only gets the clinical laboratory testing services. In pursuing this strategy, political considerations may prevent the pathologists from prevailing, but even in this instance, a direct written appeal to the Board of Directors may initiate the desired action by the PPO.

Strategy Two

ARE YOU SURE?

Too often I find local pathologists make a wrong assumption when a competing lab or a payer pressures local physicians

to refer specimens to the contracted lab provider. Because these pathologists are aware that one or more labs hold a contract, they make an assumption that the contract specifically excludes non-contract laboratory providers.

I often find the opposite to be the case. But don't expect your competitors—or the insurer—to readily admit this fact. There are many instances where non-contract pathologists can bill outpatient anatomic and cytology services to managed care companies.

Whether a lab services contract is held by one of the two major commercial labs, a regional lab, or even another pathologist-owned lab, it does not automatically exclude non-contracted pathology groups from having the right to bill for services. It is important to persistently query each managed care company to learn the specific facts about that lab services contract. In particular, determine if cytology and anatomic pathology services can be provided by a non-contract laboratory or pathology group.

Good News/Bad News

The outcome of this investigation may produce a good news/bad news situation. If pathology and cytology are included in the contract, pathologists may find that they can get recognized, but reimbursement will probably be at the level of what is paid to the commercial laboratory (very low), and may result in a marginal loss. At a minimum, this investigation into the contract's structure and terms permits you to identify the specific testing services your group wants to provide.

If cytology and anatomic pathology are not part of the contract, I recommend that you immediately approach that managed care company. Open negotiations to gain recognition as an anatomic and cytology service provider and to negotiate a reasonable fee schedule.

Even if the contract restricts all lab testing services only to the contracted lab(s), you still have viable options and should not give up. It is time to make your case that the contract should be opened to include your pathology group as a provider.

Begin with the provider relations department. If that department indicates your pathology group cannot be paid for this work, move directly to the Medical Director of the organization.

Even if the contract restricts all lab testing services only to the contracted lab(s), you still have viable options and should not give up.

Keep in mind that your goal is to educate the right decision maker. For example, if a Medical Director practiced pediatrics for several years before accepting the position of Medical Director, it is unlikely that he/she fully appreciates the professional interdependence between the surgeon and the pathologist.

If the Medical Director says no, we have been successful in immediately filing an appeal to the governing board of the managed care organization. A word of advice—don't get involved with the marketing people. They will only give you reasons why they like the single contract. We also find vice presidents and presidents to be a waste of time. They seldom provide any assistance.

Preparing To Negotiate

Before approaching a health insurer, it is crucial that you prepare a precise list of the procedure codes for which your pathology group wants the right to bill. If your group performs these procedures, interpretation of immunohistochemistry, fine needle aspiration, and flow cytometry must be included on this list.

In many cases, the insurer may indicate it does not have those testing services in their fee schedule. This provides another wedge for the pathology group. It can provide this unique service and it can educate the insurer about the level of fees needed to properly reimburse for these services.

There are other issues which can cause payers to make an affirmative decision. First, it is important that your legal counsel review state laws. That's because some states passed a managed care enabling act which requires physician access to multiple laboratories.

In most states, there is a legal requirement that the contract bidding process be open to qualified providers. If it turns out that the managed care contracting entity requested a bid for only for a universal lab testing contract, that may be justification to file an administrative appeal to the Insurance Commissioner or another regulatory body.

Strategy Three

DOCTORS WANT US

There is a third strategy that can be powerful in certain circumstances. Have physicians send letters to the managed care provider requesting that your pathology group be added to the provider panel.

This requires a some work on the part of the pathologists. Surgeons and other physicians need to be personally asked to write a letter to the managed care entity. We make a point to provide several types of sample letters, in outline form! They can flesh it out on their letterhead, sign it and send it along. The letters should note the benefits which result from using a local pathology group as a provider. (*See sidebar next page.*)

Have physicians address all their petition letters to one place at the man-

Pathologists Offer Benefits To Local Physicians

WHEN HAVING PHYSICIANS write a managed care plan asking to have the local pathology group added to the provider panel, there are several benefits which can be mentioned. They include:

- 1• Getting all tests for inpatient, outpatient, and outreach procedures from the same lab.
- 2• Speedier turnaround time for biopsies, since national labs typically take a week or longer to report results.
- 3• Improved quality of care, particularly if a pathologist is frequently asked to do formal (or informal) second opinions. The referring physician should write the payer and state clearly that he/she prefers to use the local pathology group for the initial case work-up.
- 4• Quality of reports on outpatient tests, particularly biopsies. We find it effective for a surgeon to compare a biopsy as reported by the pathology group in his hospital with the biopsy report he gets in his office from a commercial lab. Such a comparison can be stunning in favor of the local pathology group.

aged care entity—the Medical Director. He is charged with maintaining clinical quality and keeping the panel of physicians happy. Remember that it is important for these endorsement letters to be unique, even as they request the same pathology group be added as a contract provider. When Medical Directors see a barrage of nearly-identical letters, they know who initiated the letter-writing campaign.

After these letters are sent (and a check is made to insure this happened), a representative of the group should follow up with the Medical Director. Most are open to scheduling this meeting. For pathology groups that either operate their

own labs or operate under a “technical component purchase agreement,” diligent execution of these three strategies will generally result in recognition by the payer. Of equal significance, most such pathology groups negotiate fee schedules that are better than those in place for the commercial laboratory provider(s).

Have No Misconceptions

Pathologists should have no misconceptions. Each one of these three strategies can prove to be slow and time-consuming—not to mention frustrating. However, to our knowledge, these are the only methodologies that offer a pathology group the reasonable probability of gaining recognition for these laboratory services. Also, our experience teaches that it is important to follow these strategies in the sequence listed here. This maximizes the chance for success.

Here’s another secret from our experience. Obviously, each managed care plan requires a separate negotiation cycle. That can appear daunting at the start. But we’ve learned that, each time our pathology group earned recognition with one managed care carrier, it was easier to negotiate recognition with the next carrier. The same holds true for negotiating reasonable reimbursement for each contract.

Specimens Going Elsewhere

There is a reality every pathology group practice must face. The proportion of patients seen in hospitals is shrinking compared to the growth in outpatient procedures. It means that pathologists must expend extra effort to retain their access to specimens originating in physicians’ offices, in ambulatory surgery centers, and specialty hospitals. The strategies described above can be invaluable in helping local pathology groups maintain their market share. They can also spell the difference between success and failure over the long term. **TDR**

Contact Albert Giles at 856-354-0965.

Dark Index

TriPath Imaging and Ventana Sign Major Development Pact

Goal is to marry Ventana's specimen processing products with TriPath's imaging systems

IF THE NEW BUSINESS AGREEMENT between **Ventana Medical Systems, Inc.** and **TriPath Imaging, Inc.** is successful, then the anatomic pathology laboratory may have a very different look in future years.

Last week, **Ventana Medical Systems, Inc.** announced a five-year global supply agreement with **TriPath Imaging, Inc.** that involves two primary objectives. First, Ventana will put its brand on a version of TriPath's interactive histology imaging system and sell it worldwide. Second, this instrument system will be designed to run proprietary imaging assays produced by both Ventana and TriPath. TriPath Imaging will seek 510K clearance from the FDA for performance of the Ventana assays on the interactive imaging system prior to its launch in the U.S.

New Tools For Pathologists

THE DARK REPORT believes this collaboration has the potential to produce an integrated technology platform that gives pathologists a host of new diagnostic capabilities. It is the intent of both companies to provide pathologists with a way to complement cell morphology with molecular technology.

"We believe Ventana has long viewed imaging as part of the 'total solution' for the AP lab," stated Paul Sohmer, M.D., President and CEO of TriPath. "A key part of its long-term business strate-

gy is to compliment its staining solutions with an effective imaging solution.

"For TriPath Imaging, the Ventana agreement brings us two direct benefits," explained Sohmer. "One, Ventana has the largest sales force in both the United States and the world calling on anatomic pathology laboratories. It is the goal of both companies to leverage this resource to place these imaging systems in laboratories throughout the world. That gives both Ventana and TriPath an installed base of instrument systems which can run new molecular assays as they are developed by both our companies.

"Two, rapid advances in genomics and proteomics are creating a new challenge for pathologists. In order for a pathologist to extract and deliver the full depth of information possible to a clinician, he/she must have a way to correlate cell morphology studies with the growing number of molecular assays relevant to that particular case," he noted.

"Combining Ventana's stainers with TriPath's imagers allows us to provide pathologists with a way to make that correlation," said Sohmer. "This need already exists for ER, PR, and Her2Neu testing, for example."

"It is being developed as an interactive system," noted Sohmer. "The pathologist must guide the system and the supporting technology to the clinical answer. It is also 'real time.' As the

pathologist evaluates different areas of the specimen on the screen, alongside the image will be the data, including histograms and similar results.”

Molecular Cytopathology

Sohmer revealed that a molecular cytopathology system is under development. “In contrast to histopathology, which needs to analyze and correlate a variety of supporting technologies, our molecular cytopathology imaging station is designed to increase productivity. Our molecular assay for cervical cancer, for example, will be developed to be used with and without an imaging device. It will complement our FocalPoint™ slide profiler, a screening system for cervical cytology,” he said. “Technology used in both the histopathology and molecular cytopathology systems is very similar.”

For TriPath Imaging, the Ventana agreement has at least three strategic business benefits. “This expands our presence into an entirely new segment of the clinical market,” explained Sohmer. “We will have a place in the anatomic pathology (AP) lab, just as we now have a place in the cytology lab.

“Next, this agreement provides TriPath with an opportunity to generate new revenue streams directly from the fee-for-service instrument placements sold to Ventana,” he continued. “As these instruments come into clinical use, it then supports the sale of proprietary assays developed by Ventana and TriPath.”

Two Molecular Assays

Sohmer noted that, in August, TriPath released two new molecular Research Use Only (RUO) products to select research centers for cancers of the cervix and breast. “These assays are available for research,” he said. “We expect to begin clinical studies early next year and file with the FDA for approval in late 2005.”

THE DARK REPORT considers the Ventana/TriPath collaboration to be a significant event. It should lead to an

TriPath, Digene File HPV Docs with FDA

Even as TriPath Imaging announced its agreement with Ventana Medical Systems, it was taking steps to advance its liquid preparation Pap smear product.

On August 26, 2004, TriPath filed supplemental data with the **Food and Drug Administration** (FDA) to allow TriPath's SurePath™ Test Pack as the specimen-collection medium for **Digene Corporation's** hc2 High-Risk HPV DNA Test™. Both companies want FDA approval to use their products in this complementary fashion.

Just last Thursday, **Digene Corporation** disclosed it had filed its own premarket approval (PMA) supplement application with the FDA to allow use of TriPath's SurePath™ Test Pack as the specimen-collection medium for Digene's hc2 High-Risk HPV DNA Test™.

Typically, the FDA has 180 days to issue a ruling on these types of applications. For that reason, a decision on these PMA requests is not expected until the first half of 2005.

integrated system of specimen processing and specimen diagnosis in the anatomic pathology laboratory.

Of equal significance, these products are designed to support molecular diagnostic technologies as they evolve. The profession of anatomic pathology is at the earliest stages of a clinical evolution. Cell morphology as the primary source of AP knowledge is increasingly being supplemented by molecular (genomic/proteomic) analysis.

At some point, advances in molecular diagnostics may cause it not to supplement cell morphology, but to supplant it as the primary source of diagnostic information.

TDR

Contact Paul Sohmer, M.D. at 336-290-8743

INTELLIGENCE

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



Ventana Medical Systems, Inc. now has access to

Qdot® nanocrystal technology for *in vitro* diagnostic applications in anatomic pathology and cytology. Ventana recently licensed the technology from **Quantum Dot Corporation** (QDC), based in Hayward California. It will use Qdots to create “next generation rapid, quantitative, and multiplexed assays for cancer diagnosis and disease management.” Qdots have the potential to support a multiplexed assay with a surprisingly large number of analytes. Some scientists conjecture that Qdots might prove feasible for use with *in vivo* testing, once their safety in the human body is demonstrated.

MORE ON: Qdots

Clients of THE DARK REPORT with long memories will remember our coverage of Quantum Dot in its emerging phase. The company developed nano-sized semiconductor crystals with unique properties. A single light source will light up all sizes of Qdots, which produce sharp colors at specific frequencies. Qdots have great potential for multiplex assays, both in research and clinical diagnostic applications. (See TDR, February 14, 2000.)

15 DISEASES CAUSE HALF THE ANNUAL RISE IN HEALTHCARE COSTS

Here is a provocative finding that puts laboratory testing front and center in the battle to control spiraling healthcare spending. The **U.S. Department of Health and Human Services** (DHHS) studied the healthcare costs incurred by 60,000 patients. It determined that just 15 medical conditions accounted for one-half of the inflation-adjusted growth of \$200 billion in healthcare spending between 1987 and 2000! The cost increases were driven by one of two main factors: increased costs of new drugs and/or new medical technology to treat the ailment; or, increased prevalence of the conditions among the population.

ADD TO: 15 Diseases

Five diseases were responsible for the largest cost increases. They are heart disease, asthma, mental disorders, cancer, and hypertension. Heart disease is an example of “increased cost to treat” due to new drugs and

new technology. Cost per case increased by 70% between 1987 and 2000. Mental illness is an example of increased incidence. The rate of treatment for mental disorders almost doubled during the same 14 years, reaching 8,575 cases per 100,000 people. Lab testing is expected to play a key role in minimizing health costs by aiding early detection and guiding appropriate therapies

TRANSITIONS

- **LabOne, Inc.** announced that Chief Financial Officer John W. McCarty resigned his position, effective March 31, 2005. McCarty plans “to travel abroad and pursue other interests.” McCarty will aid LabOne in its efforts to recruit a new CFO.

- There is a new Laboratory Administrator at **Avera McKennan Healthcare**, a four-hospital health system based in Sioux Falls, South Dakota. Leo Serrano joined the organization in August. Serrano was formerly Administrative Director of Laboratory Services at **West Tennessee Healthcare**, located in Jackson, Tennessee.

*That's all the insider intelligence for this report.
Look for the next briefing on Monday, October 11, 2004.*

Save the Date!

EXECUTIVE WAR COLLEGE

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UPCOMING...

- ***Measuring Anatomic Pathologist Productivity in Private Practice and Academic Settings.***
- ***America's Best Lab Outreach Programs: Shared Secrets Behind Their Success.***
- ***Molecular Diagnostic's New Turn in the Marketplace Road Means Better Fees for Labs.***
- ***Laboratory IT Breakthrough: Lab Competitors Collaborate To Docs' Benefit.***

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