

From the Desk of R. Lewis Dark...

THE DARK REPORT

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

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Commentary & Opinion by...

R. Lewis Dark

Founder & Publisher



Complete Human DNA Profiling as a STAT Test

MOST OF YOU ARE UNFAMILIAR WITH A NEW SCIENTIFIC PRIZE that is in the planning stage. On January 27, *The Wall Street Journal* published a story that disclosed the plans of the **X Prize Foundation** to award a prize, totaling between \$5 million and \$20 million, to the team that first decodes the full DNA of 100 or more people in just a few weeks.

If the X Prize Foundation seems familiar to you, it is the same group that awarded the \$10 million prize to the team that developed SpaceShipOne, which in October 2004 became the first manned space vehicle to launch from earth, reach space and return safely twice in one week.

What is intriguing about this planned new award for DNA sequencing is that J. Craig Venter, Ph.D., is collaborating with the X Prize Foundation. It was Venter who launched the private project to map the human genome in 1998 and developed ways to accelerate gene sequencing. (See *TDR*, June 15, 1998.)

The goal of this new prize is to encourage development of faster, cheaper gene-sequencing technologies. According to *The Wall Street Journal*, today's technology can allow a team to sequence the entire human genome in about six months, at a cost of \$20 million. Experts believe this cost may be driven down to \$100,000 within a few years.

My fellow readers, can you imagine what this technology might eventually allow us to do? For a reasonable cost, a full human genome could be sequenced in minutes and that clinical information delivered to the patient's physician. In our life times, we may see complete human DNA profiling done as a STAT test. Boy, wouldn't that change laboratory medicine the way we know it today? It could happen. After all, in the lifetime of some of our oldest doctors, they have seen the discovery of DNA lead to useful genetic tests and therapies.

Of course, the skeptics among you have good arguments why it may take decades for anything like this to happen. I understand that viewpoint. However, as the industrial age yielded to the information age in recent decades, it seems like the genetic age may supplant the information age at an ever-accelerating pace. Maybe Star Trek's vision wasn't so far-fetched... Nurse Chapel, would you please bring the Tricorder to Bones?

TDR

Many Trends in AP Spell Lots of Change Ahead

Our biannual list expands to 11 trends, larger number points to swifter evolution

CEO SUMMARY: *Every second year, THE DARK REPORT releases its list of key trends in anatomic pathology. These trends help shape an understanding about the state of the pathology profession. Our current list includes 11 identifiable trends. This is not an auspicious sign for pathologists who prefer things to remain the same. Eleven distinct trends are themselves evidence that plenty of important changes are happening.*

By Robert L. Michel

WHAT'S AHEAD for the pathology profession in the next few years? Once again, it's time for THE DARK REPORT to release its list of the most important anatomic pathology trends.

At the start of every second year, we provide pathologists and lab administrators with our best assessment of the most important strategic drivers in the anatomic pathology (AP) marketplace. Our list for 2006 is the third, following our 2002 and 2004 lists. (*See TDRs, January 7, 2002 and January 12, 2004.*)

As you will see, this year THE DARK REPORT identifies and analyzes 11 distinct trends. That fact may be notable in its own right, since we presented six trends in 2002 and eight trends in 2004.

Each list we present to the pathology profession has been distilled down to the essential items we believe to be most significant. Our objective is to help you focus your strategic thinking on the critical few items that will have the greatest positive impact on your pathology group practice or laboratory.

For that reason, the creep in the number of anatomic pathology trends—six in 2002, eight in 2004, and 11 in 2006—is significant. I believe these increases reflect how the American healthcare system is changing. Not only are there more disruptive forces at work, but their effects are more rapid. Collectively, both factors reinforce each other and accelerate the pace of change currently seen in the healthcare system.

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THE DARK REPORT'S AP Trends for 2002 and 2004

HERE ARE ANATOMIC PATHOLOGY TRENDS identified by THE DARK REPORT in the years 2002 and 2004. They provide a report card on our predictions and strategic analysis. They also show how early in the market curve our clients were alerted to key trends.

2002 Anatomic Path Trends

- 1...Influence of national anatomic pathology firms**
- 2...Consumers find pathology**
- 3...Pathology centers of excellence**
- 4...First signs of genetic and molecular pathology**
- 5...Internet and telepathology create new opportunities**
- 6...Shortage of pathologists and technologists**

2004 Anatomic Path Trends

- 1...Patient safety and measuring provider outcomes**
- 2...Move to consumer-driven healthcare**
- 3...Six Sigma and Lean arrive in pathology labs**
- 4...National market for anatomic pathology services**
- 5...Molecular pathology on the increase**
- 6..."Real time" anatomic pathology is approaching**
- 7...Recognized shortage of pathologists and techs**
- 8...Age of the pathologist subspecialist**

To help you put the 2006 pathology trends into perspective, the sidebar above contains AP trends we identified in 2002 and 2004. You will see some consistent themes, like molecular diagnostics, pathology subspecialization, and a growing role for consumers.

Strategic Assessment

Of course, some of this year's trends are obvious to any keen observer of the American healthcare system. What you'll find most valuable is our assessment of how each trend is likely to affect the anatomic pathology profession. This is useful analysis, designed to focus your strategic thinking.

Each time THE DARK REPORT publishes these lists of trends in anatomic pathology and clinical laboratory, we recommend that clients and regular readers use them for strategic planning sessions. One trait of successful laboratories is a regular review of the busi-

ness variables and market changes which affect the lab's strategic thinking. Feedback from clients in past years tells us that our list of AP trends invariably triggers new insights.

It is difficult to prioritize this list from most important to least important. But I recommend that you look at each anatomic pathology trend as both a threat and an opportunity. The threat generally comes when a lab or pathology group does nothing in the face of significant changes which can have a negative impact on the lab's finances.

The opportunity comes from grasping a trend and positioning your pathology group to ride its crest—creating added value for your clients and generating additional revenue for you.

Finally, it's my sense that these 11 trends point to a faster ride in the second half of this decade than in the first.

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Medicare/Private Payers Attack AP

MOST OF US ARE FAMILIAR with the Richter Scale to measure the strength of earthquakes. Each point on the Richter Scale represents a ten-fold increase in energy.

From that perspective, the discovery in December 2005 that a Medicare contractor was proposing to restrict use of CPT 88305 (Level IV—Surgical Pathology, Gross and Microscopic Exam) to two units of service per day per patient may qualify as a “Richter 9.0” shock to the pathology profession. (*See TDR, January 16, 2006.*)

There could be no more devastating choice of pathology CPT codes for a restriction of service. With one recommendation, Medicare’s contractor has proposed a change which has profound consequences for the pathology profession, in at least three dimensions. First, it contradicts accepted clinical “best practices” for a variety of procedures—many of which are performed by surgeons as part of a treatment protocol designed to save or extend life.

Second, the proposed restriction of service has the potential to financially cripple many laboratories and pathology group practices. For Medicare patients, this would reduce both access and the quality of care for procedures that require pathology services.

Third, if the restriction on 88305 service is implemented, it has the potential to raise the cost of healthcare to Medicare patients. Every time a surgery procedure generates more than two tissue specimens for analysis by pathologists, that Medicare patient is likely to be asked to sign an ABN (Advance Beneficiary Notice)

and pay out-of-pocket for the additional 88305 procedures that go unreimbursed by Medicare.

However, as the pages of THE DARK REPORT have noted too frequently over the past 24 months, the Medicare and Medicaid programs are not the only sources of attack on pathology services. Efforts by numerous managed care plans to cease paying for clinical pathology professional services are numerous—and have a negative financial impact on many pathology groups.

In a real sense, the collective actions by Medicare/Medicaid bureaucrats and private health insurers to arbitrarily reduce coverage and reimbursement for anatomic pathology services can be considered a war against the pathology profession.

This particular war is about money. Steady increases in the cost of healthcare put both government and private health programs in a bind. It motivates them to try all sorts of methods to reduce what they pay doctors. Pathologists are at a disadvantage in this war because they lack the physician’s most important ally: patients!

Because pathologists don’t personally see patients, they lack the opportunity to encourage patients to lobby government officials, complain to private health insurers, and raise objections with employers on issues vital to the long-term benefit of the pathology profession.

From this perspective, 88305 is just the latest salvo in an ongoing war over who gets access to the inadequate quantity of dollars available to pay for healthcare services.

Consumers Are Becoming "Payers"

FOR THE PAST SIX YEARS, these pages have regularly reported on the growing numbers of activist consumers. By definition, these are individuals ready and willing to assertively manage their health.

This trend is now intersecting with another trend: that of employers raising the co-pays, deductibles, and out-of-pocket expenses their employees are required to pay during the year before health insurance coverage is triggered.

Consumer-Directed Health Plans (CDHPs) is the term most frequently used to describe this trend. HSAs (Health Savings Accounts) are probably the purest form of CDHPs. A typical HSA will require the individual to pay out-of-pocket expenses of \$1,000 to \$2,500 per year before the health policy begins to pay for services. A family HSA has deductibles of up to \$5,000 before health insurance payments begin. (*See TDR WHITE PAPER, December 19, 2005.*)

The CDHP trend will have two distinct influences on consumer behavior, both of which will change today's anatomic pathology marketplace. First, when an activist-consumer enrolls in an HSA, they increase their ability to manage their own care, since they will pay significant amounts of money directly to their care team. THE DARK REPORT believes that CDHPs in general, and HSAs specifically, will encourage activist-consumers to be even more aggressive in managing their own care.

Second, it is likely that the similar effect will happen to non-

activist consumers. As they find themselves enrolled in CDHPs, the requirement that they spend a larger amount of their money on health-care is likely to encourage these individuals to also become savvy buyers of their healthcare.

For anatomic pathologists, this is a situation with negatives and positives. The big negative is the need to collect lots of money directly from consumers. This will be a challenge for pathologists because they don't see patients. Pathology group practices should study this situation and design systems to help them bill and collect directly from consumers enrolled in CDHPs.

On the positive side, consumers will have increased freedom to choose their healthcare providers. There is evidence that many informed consumers view anatomic pathologists as care team specialists. These consumers will actively seek out and select accomplished pathologists to diagnose their case. In this scenario, CDHP-insured consumers will have few constraints on their selection of physicians. Provider access via managed care contract won't be an issue. This can be a favorable development for pathologists.

Pathology groups located in cities where major employers are offering CDHPs and HSAs to their employees will be first to experience the consequences of this trend. One early sign of change is likely to be a steady increase in patient bad debt as pathology groups begin serving CDHP-insured patients who will be responsible for paying 100% of their pathology charges.

Histology Automation Is Arriving

IT PROMISES TO BE A REVOLUTION! The nation's three leading manufacturers of products for histology are introducing instrument solutions that automate manual processes in the histology laboratory.

Alphabetically, **Dako, Inc., Sakura Finetek, Inc., and Ventana Medical Systems, Inc.** are each introducing automated solutions for applications in the histology laboratory. Such timing is not a coincidence. There is a convergence of technologies that miniaturize, simplify, and control the products and steps used in histology work flows.

The arrival of automated solutions for histology is likely to shake up the status quo in multiple ways. Until now, the histology laboratory has typically been organized around manual work processes. It is a labor-intensive department within the laboratory organization.

By contrast, the automated histology laboratory will be capital-intensive. Up-front money is required to acquire the equipment, train the operators, and integrate the automated systems into the histology laboratory's work flow.

Histology managers interested in deploying automation solutions should be ready to accept and understand two differences in their job responsibilities. One will be the need to develop a capital spending budget and convince higher-ups that investing money in histology automation solutions is both good medicine and good use of limited capital.

The other will be the need to acquire the management knowledge required to understand how automa-

tion works and how to design histology laboratory workflow to take best advantage of automation.

Because of the importance of this trend, the *Executive War College on Lab and Pathology Management* is offering a special one-day program titled "Building the Automated 21st Century Histology Laboratory" in Miami, Florida on May 5, 2006. It will mark the first time that laboratories using the automated systems of Dako, Sakura Finetek, and Ventana Medical Systems will publicly report on their successes and lessons learned.

It is uncertain how swiftly histologists will embrace automation. Although the popular conception of automation is that it replaces jobs, there is a different reality. Automation eventually creates more jobs and requires more skills from the operators. Simply put, histologists, instead of performing manual procedures, will use their technical skills and medical knowledge for more sophisticated purposes.

There is likely to be another important benefit from automation in the histology laboratory. Automated systems will make it easier for the laboratory to expand its menu of tests, stains, and the like, while improving quality and reducing turnaround time. These are favorable outcomes for pathologists and the physicians who refer specimens to the histology laboratory.

Perceptive pathologists will recognize that automation in histology is likely to also trigger related changes in the daily work patterns of the anatomic pathologists served by the histology laboratory.

Specialty Docs Target AP Services

ANATOMIC PATHOLOGY SERVICES are in the cross-hairs of specialist physicians, particularly urologists, gastroenterologists, and dermatologists.

During the past three years, the pathology profession saw an explosion of interest among these physicians in ways that enable them to capture revenues from the anatomic pathology services provided to their patients.

The intensity of this trend was first revealed when THE DARK REPORT published its award-winning exposé of anatomic pathology (AP) laboratory condominium complexes. During the 18-month period between January 2003 and June 2004, as many as 100 urology, gastroenterology, and dermatology groups had purchased an AP lab condominium. Often the specialty group which owned the AP lab condo was located in a state hundreds or thousands of miles from the AP condo lab complex. (See *TDRs*, July 19, 2004 and August 9, 2004.)

In addition to this extraordinarily-rapid acceptance of the AP laboratory condominium business model, larger specialty groups have been building AP laboratories within their own clinics. Other specialty groups have approached local pathologists with proposals to joint venture an anatomic pathology laboratory inside the specialty doctors' office.

Another approach is for specialty physicians to establish their own laboratory to perform pathology technical services. The pathology professional service can then be done by a pathologist employed by

the physician or by contract with a local pathology group.

Collectively, these different types of business propositions are siphoning off the high volumes of specimens that many community hospital-based pathology groups rely on to financially sustain their practice.

It may prove difficult for the pathology profession to successfully counter this trend. Dermatology provides a relevant example. Over the past two decades, specialization in dermatopathology services has advanced to the point where dermatopathologists can establish themselves in solo practice and build a substantial business. In recent years, larger dermatology groups have taken steps to hire their own dermatopathologist and perform all their anatomic pathology work as an in-clinic service.

In cases where a specialty group operates a sizeable ambulatory surgery center or endoscopy center, there is often enough anatomic pathology work to support a part-time or full-time pathologist. Specialty physicians who own these facilities are taking steps to capture the anatomic pathology revenues generated from patients treated at these centers.

The interest of specialty physicians in capturing anatomic pathology revenues will not decrease. At the meetings of urology and gastroenterology associations, there are public and private presentations by individuals and businesses offering to help physicians establish their own anatomic pathology laboratory. That fuels the interest of specialty physicians in this business model.

Measure Outcomes for Quality & Pay

BEFORE LONG, all laboratories and even individual pathologists will have a quality and outcomes scorecard. This information will be used for two purposes.

First, employers, payers, and patients will use the scorecard to evaluate and select providers. Second, health insurers and government health programs will use measures of quality and outcomes to establish pay-for-performance programs. These programs will reward providers who meet and exceed the goals of such programs.

For that reason, these programs have the potential to radically reshape the anatomic pathology profession. As it stands now, government health programs and private payers have no effective way to measure the clinical effectiveness of pathologists and compare one to another. Even within the pathology profession, there is much debate about whether such a "rating system" could ever be developed.

Regardless of debate within the pathology community, it is likely that healthcare's drive to improve patient safety, reduce medical errors, and boost healthcare outcomes will lead to a solution for measuring the effectiveness of individual physicians, including pathologists.

That's because, across the American healthcare system, there are researchers, payers, and provider organizations gathering measurement data in great detail. In some cases, this data is used to establish a patient safety baseline, then measure progress at improving patient safety. In other cases, the measurements are

part of evidence-based medicine projects. The goal of these projects is to determine the clinical effectiveness of the medical procedure being studied.

Measurements are at the heart of pay-for-performance programs and the **Centers for Medicare and Medicaid Services (CMS)** will be a major factor in this trend. In recent months, CMS announced the results of the first full year of its three-year hospital pay-for-performance demonstration project. (*See TDR, December 5, 2005.*)

CMS also launched a demonstration project for physician pay-for-performance last April. It is likely that the federal healthcare agency will report the first-year results, possibly as early as this summer.

THE DARK REPORT believes that providers will be measured in two different ways. Currently the emphasis is to measure whether clinicians consistently follow recommended guidelines when treating their patients. The ideal goal is that all physicians consistently follow treatment guidelines with all their patients, all the time.

This would reduce variability of care—across different regions of the country and across different physicians. As that happens, the quality of care is expected to significantly increase.

The second stage of the measurement trend will be to measure the quality of outcomes by individual providers and physicians. Rankings will be published to help employers, payers, and patients select hospitals, physicians, pathologists, and laboratories that deliver superior outcomes.

Client Bill & Discounting Erodes Comp

COMPETITION for anatomic pathology (AP) specimens is intensifying. Across the United States, more anatomic pathology providers are willing to use client account billing and aggressive discounting to gain new sources of specimen referrals.

THE DARK REPORT considers this trend to be distinct and different than the trend of specialist physicians wanting to establish in-house AP laboratories. Client billing and deeply-discounted pricing pressures are frequently the direct result of anatomic pathology companies entering local markets and using these sales tactics to win clients away from community hospital-based pathology groups in that region.

This is a trend that originates within the laboratory industry. It is directly related to the formation of new anatomic pathology companies. These new AP providers must enter the marketplace and attract the specimens and revenues that are essential to business survival. Too often, these companies emphasize "lowest price" as the way to attract new physician accounts.

It should be mentioned that client billing arrangements and deeply-discounted pricing can create compliance risk—both for the AP company that offers the arrangement and for the physicians who accept the terms of the arrangement and benefit directly from such pricing terms. Despite the multiplicity of federal and state regulations governing the business arrangements and pricing between laboratory and

referring physician, competitive pressures always seem to lead a few lab companies to bend the rules in ways that create competitive advantage for them—regardless of compliance risk.

As anatomic pathology companies come into the marketplace and offer client billing terms and deeply-discounted pricing that appeals to some physicians, there is another negative consequence to this sales tactic. It changes the expectations of referring physicians. It teaches them how to value their anatomic pathology referrals and encourages them to play different AP providers against one another.

This increases the pricing pressure on local pathology group practices. Not only do they have national AP companies coming into their community and trying to convince long-time clients to switch—but those same national AP companies make local doctors aware that they can negotiate client billing terms and pricing for the AP services provided to their patients.

Aggressive use of client billing and deeply-discounted pricing is a significant factor in eroding the widespread collegiality which was common in the pathology profession in earlier years. These are business development tactics which are not favorable to the long-term financial health of the pathology profession.

For this reason, in many states, pathologists are working with their state legislature to enact laws which constrain and restrict use of client billing and deeply-discounted pricing.

Shortage of Pathologists & Histotechs

FROM COAST TO COAST, laboratories large and small report their inability to recruit enough histotechnologists to fill authorized positions. In the face of rising demand for histology-based laboratory testing, this is a crisis of yet-unrecognized proportions.

When it comes to pathologist staffing, it's a different situation. Over the past decade, there's been plenty of public debate about whether medical schools in the United States are training the numbers of pathologists needed to support the nation's healthcare system. But it is difficult to locate published studies and detailed projections about the number of pathologists needed and whether the educational pipeline is producing adequate numbers of new pathologists to meet this demand.

In December, THE DARK REPORT completed a three-city tour of Australia, visiting five laboratories and participating in a laboratory conference. Throughout this trip, pathologists and laboratory directors commented on the shortage of pathologists in Australia. Although not yet at a crisis level, the statistics show that each year there is a labor supply mismatch. Many fewer pathologists complete their medical training and enter practice annually than the number of pathologists known to have retired, switched specialties, or left the country.

In New Zealand, there is an acknowledged, existing shortage of pathologists. This nation of four million people has vacancies for pathologists which go unfilled. The

healthcare system has yet to find a solution to the problem. Pathology training programs must compete with other sectors of healthcare for public funding, and it is recognized that there is not enough money available to resolve this shortage of pathologists.

Many pathologists believe a similar situation exists in the United States, and that medical schools are not producing enough pathologists to meet existing and future needs. What clouds the picture is immigration, since physicians from other countries relocate to this country and practice medicine here.

All sectors of laboratory medicine do agree on one point. With large numbers of baby-boomers approaching retirement and with demand for healthcare services increasing each year, it will be increasingly difficult for laboratories to recruit and retain enough technically-trained individuals, whether the need is pathologists, Ph.D.s, medical technologists, cytotechnologists, or histotechnologists.

It should be noted that baby-boomers were consistent in their willingness to work hard and to work many hours each week. The generations which follow the baby-boomers do not have that same work ethic. Generation X, for example, likes to work hard—but for a defined number of hours. Its members then prefer to spend the balance of their time pursuing personal interests. This work/play ethic may mean that the lab industry will have to attract and train even greater numbers if they are to be adequately staffed.

Generation X Impinges on Boomer APs

HERE'S AN ANATOMIC PATHOLOGY TREND currently getting little public recognition, but already changing practice dynamics in many pathology groups around the country.

Generation X is now challenging the Baby Boomer Generation. This wider national trend is playing out within the anatomic pathology profession. The front edge of Generation X pathologists has reached the age of 41. These anatomic pathologists have achieved professional maturity.

With a decade or more of service within their group, Generation X pathologists are insisting that senior practice partners cede them more influence on group practice matters. Because of differences in work styles and life outlooks between the Boomer and X generations, this demand for more power in the business management of the practice frequently triggers conflict and stirs emotions.

Birth year and attitudes are what distinguish Generation X from Baby Boomers. Generation X is comprised of individuals born from around 1964 (about the time the baby boom turned into the "baby bust") and through 1981. The oldest members of this generation began graduating from medical school in the late 1980s.

Simple demographics forms the basis for increasing confrontation between boomers and X'ers. Across the anatomic pathology profession, Baby Boomer pathologists are fast-approaching their retirement years.

Because of their years in practice, they are senior partners in the pathology group practice and accus-

tomed to leadership roles. Census data puts the number of baby boomers at about 77 million people. This is 27.5% of the nation's population. By contrast, Generation X numbers about 50 million people and makes up 17% of the population.

Currently the **College of American Pathologists** has approximately 13,000 board-certified pathologists. Rough demographic calculations that exclude people under 29 years old provide an intriguing look at how the pathology profession in the United States is aging.

Extrapolating the ratios of Gen X and Boomer in the general population to the CAP membership generates numbers that suggest about 3,800 pathologists are Generation X. By contrast, Baby Boomers appear to make up approximately 5,900 pathologists. The balance, about 3,300 pathologists, would be 60 years or older. As a point of reference, someone born in 1964—the dividing year between Boomers and X'ers—is 41 years old at the start of 2006.

The partner politics of private pathology group practices will be interesting to watch over the next decade. Boomers are used to control. They work long hours to achieve desired lifestyles. By contrast, X'ers work their designated hours, then take off to pursue lifestyle interests.

As they accumulate years of service in a pathology group, X'ers will want business decisions to reflect their preferences. That may make decision-making in private pathology groups more interesting and rancorous as Boomer pathologists approach retirement.

Six Sigma/Lean Push into Path Labs

IT SEEMS THAT THE “QUALITY MANAGEMENT CAT” is out of the bag. Across the United States and in other developed countries, growing numbers of laboratories are beginning to embrace quality management methods.

It was in 2003 when clinical laboratories in three major health systems boldly became first to use Lean and Six Sigma principles to make over their high-volume core chemistry and hematology laboratories. Now Lean and Six Sigma methods are finding applications in anatomic pathology laboratories and pathology group practices.

At the upcoming *Executive War College on Laboratory and Pathology Management* (May 3-4, 2006 in Miami), the first case studies of Lean projects in histology laboratories will be presented. Effective use of Lean and Six Sigma principles generated significant benefits for the centralized histology laboratory that supports the eight hospitals affiliated with **Alegent Health System** in Omaha, Nebraska.

It is only in the past year that such projects have found their way into histology laboratories, and usually only in hospitals where the clinical lab has experience with Lean and Six Sigma techniques. The histology lab’s “Lean makeover” is usually a second or third generation project and incorporates the clinical staff who have learned the techniques, earned black belt designations, and have the experience to design and execute the project.

In a similar fashion, anatomic pathology group practices affiliated

with hospital laboratories that have incorporated Lean/Six Sigma principles have the opportunity to participate in the planning and execution of such projects in the clinical laboratory. This gives them first-hand experience in how these quality management tools are used in planning and implementing projects to improve work processes, reduce errors, increase productivity, and cut back on waste.

Probably the leading example of sophisticated use of quality management principles is at **University of Miami/Jackson Memorial Hospital** in Miami, Florida. In recent years, the pathology department has developed a “single piece work flow” system for collecting, processing, and diagnosing pathology specimens.

This system allows pathologists to provide surgeons with a diagnosis in as little as two hours—frequently just as the patient is wheeled out of recovery! Clinicians love it and patients appreciate hearing their diagnosis so soon.

Azorides Morales, M.D., Pathology Chairman at University of Miami, will be at the *Executive War College* to share how this system has improved clinical care and increased the respect physicians extend to pathologists. He will also host a site visit of his laboratory during its operating hours for *War College* attendees.

Across the country, pathology groups and histology laboratories are becoming aware of the power of quality management systems to improve clinical quality, reduce turnaround time, cut costs, and boost productivity.

Soon to Explode: Molecular Markers

"MOLECULAR PATHOLOGY IS on the ascendency." That is a quote from our last list of anatomic pathology trends, published in THE DARK REPORT on January 12, 2004.

Diagnostic technologies which incorporate analysis of DNA, RNA, and proteins are entering the clinical marketplace in ever-growing numbers. At this stage, the flow of new molecular assays is a relative trickle. But experts confidently predict that a flood of new molecular technologies will soon be approved for clinical use.

Molecular diagnostics will alter existing practice patterns in anatomic pathology in several ways. Probably the most significant change will be to break down the traditional walls between the clinical laboratory and the anatomic pathology department. That's because molecular assays can use a variety of specimen types. Some of these specimens may be processed and imaged for review by a pathologist. Others may be processed through an instrument that produces data sets that require interpretation, but not a visual evaluation.

For certain types of case work-ups, both molecular and morphological analysis must be conducted by the pathologist. The data must then be integrated to produce the diagnosis. This is true of a number of molecular assays now in clinical use.

Expansion of the molecular diagnostic test menu is likely to mean less microscope time for anatomic pathologists. Instead of spending hours at the microscope

looking at slides, pathologists are likely to find themselves assembling test data from a number of assays, gathering specific clinical background on the patient from the referring physician, and using all this information to produce a diagnosis.

Breast cancer may be an early example of how molecular assays will change long-standing pathology practice patterns. Genetic-based technologies now support at least three ways to evaluate a patient for her risk of breast cancer. Several years ago, **Myriad Genetics, Inc.** introduced its BRACAnalysis® test for determining a patient's risk of breast and ovarian cancer based on detecting mutations in the BRCA1 and BRCA2 genes.

In 2004, **Genome Health, Inc.** began offering its Oncotype DX™ breast cancer test. This test predicts the recurrence risk and ability to respond to certain therapies. Within 24 months, **TriPath Imaging Systems, Inc.** expects to be in the market with its ProEx Br panel of biomarkers. These are monoclonal antibodies designed to predict the recurrence of certain types of breast cancer. There is also the Her2Neu test, a molecular assay used to determine the potential effectiveness of Herceptin therapy.

These examples in breast cancer diagnostics illustrate how molecular assays will increase the complexity of developing a patient's diagnosis. However, molecular pathology will also increase the importance of the pathologist to both the referring physician and the patient.

Specialization of Anatomic Pathology

THIS TREND HAS BEEN UNDER WAY for almost two decades. Within the physician community, there is growing demand among physicians to have a subspecialist-pathologist evaluate cases.

Reinforcing this trend are consumers. Well-educated and intensely involved in their health, these individuals research intimate details about their diseases and want nationally-recognized clinicians to consult on their cases.

On their own, many of these consumers learn which pathologists are recognized experts in their disease. They often ask their physician to send specimens directly to the subspecialist pathologist for an opinion.

The pathology profession should recognize how these two phenomena change today's marketplace status quo. On the demand side of the clinical transaction, there are an increasing number of physicians, along with a growing number of patients, who will take active steps to direct their specimen referrals away from the generalist pathologists in their community and send the case to a national or international pathologist subspecialist.

Moving to the supply side, the past decade has seen the emergence of regional and national anatomic pathology companies. These companies are organized specifically to sell specialty anatomic pathology expertise. They also employ large sales forces to call upon office-based physicians and convince them to redirect specimen referrals away from local pathology groups and to their company, with its advertised subspecialty

expertise. During the 1990s, **IMPATH, Inc.**, **UroCor, Inc.**, and **DIANON Systems, Inc.** were first to exploit this business model, with spectacular short-term successes in capturing specimen volume from existing pathology groups.

More confirmation of the market's move to pathology subspecialty expertise comes from physician recruiting firms. Professional recruiters tell **THE DARK REPORT** that generalist-pathologists are nearly impossible to place. But if a pathologist has a degree of subspecialty expertise in at least one clinical area, then placement is very easy.

THE DARK REPORT predicts that the pathology profession will continue to place greater value on the pathologist-subspecialist over the pathologist-generalist. In addition to the demand and supply forces listed above, there is the explosion of knowledge now happening in medicine. To stay up with advances in any area of medicine, pathologists, like other physicians, will need to concentrate on specific areas of interest and expertise.

Further, technology innovations in computer hardware, software, and the Internet make it faster, easier, and cheaper to digitize pathology images and transmit them to any location in the world—in real time. This can actually be a positive development for local pathology groups. Local pathologists can continue to serve their community. At the same time, digital delivery of images can allow them to build a subspecialty practice fed by specimens from throughout the nation.

Sonora Quest Receives Highest AZ Quality Award

Only healthcare provider ever to receive Arizona's Governor's Award for quality

CEO SUMMARY: After several years of intense effort to implement quality management systems and Six Sigma techniques throughout its organization, Sonora Quest Laboratories earned the Arizona Quality Program's highest honor—the Governor's Award for Quality. This is an accomplishment without precedent in the laboratory industry, either in the United States or internationally.

BY RECEIVING THE ARIZONA QUALITY PROGRAM'S "Governor's Award for Quality"—the state's highest quality honor—**Sonora Quest Laboratories** further bolsters the argument that it is one of the nation's highest quality clinical laboratories.

It is also a singular achievement. **Sonora Quest Laboratories (SQL)** of Tempe, Arizona, is one of just six companies to have been so honored in Arizona. It is also the only healthcare provider in the history of the Arizona Quality Program to receive the "Governor's Award." Moreover, the last time an Arizona company won this award was four years ago, in 2001. SQL's achievement was recognized on December 15, 2005, through the presentation of the Governor's trophy at the State Quality Awards ceremony.

Sonora Quest's achievement provides an excellent case study of continuous quality improvement in action. In 2004, THE DARK REPORT was first to disclose to the lab industry that Sonora Quest Laboratories had been awarded

the "Pioneer Award" by the Arizona Quality Program. In so doing, it was the first healthcare provider to earn that recognition in Arizona. (See TDR, September 20, 2004.)

Both awards recognize SQL's commitment to continuous improvement and its rigorous deployment of quality management systems throughout its organization. The Arizona Quality Awards Program is based upon the same criteria used by the Baldrige Award program maintained through the U.S. Commerce Department.

Sonora Quest Is A JV

Sonora Quest Laboratories is a joint venture LLC between **Banner Health**, the largest healthcare system in the state of Arizona, and **Quest Diagnostics Incorporated**, the nation's largest clinical laboratory company. SQL is also part of an integrated laboratory network that includes **Laboratory Sciences of Arizona LLC (LSA)**, which manages seven hospital laboratories for Banner Health. SQL has grown 226% since 1998.

"The Governor's Award for Quality recognizes organizations that achieve three milestones," explained David A. Dexter, who serves as President and CEO at Sonora Quest Laboratories and **Laboratory Sciences of Arizona**, and is managing director for Quest Diagnostics in Arizona. "First, there must be mature and fully-deployed quality systems within the organization's operations. Second, the organization must demonstrate a commitment to continuous improvement. Third, the organization must have achieved a sustained and significant record of performance."

"In the truest sense, this is not an award that is 'won.' It is an award that is 'achieved.' Sonora Quest Laboratories is the first lab in this country to achieve its state's top honor for quality," he observed.

Interest In Quality Systems

Growing numbers of laboratory directors and pathologists have become interested in using quality management systems such as Lean and Six Sigma in their laboratory organizations. For that reason, the experience and successes of SQL are highly instructive.

"We used Six Sigma to fundamentally reinvent our lab operations," Dexter stated. "The process is conceptually simple: identify, quantify, and improve by simplifying work flow and work processes, eliminating waste and reducing cycle time."

"There are two fundamental keys to success with quality management initiatives," he continued. "First, the ongoing commitment must come from the CEO level. Half-way or half-hearted efforts will not work."

"Six Sigma Quality requires embracing the philosophy that we continuously strive to achieve significantly higher levels of performance," observed Dexter. "Once the philosophy is adopted and the process is implemented, the continuous improvement becomes systematic."

"The second key to success is an effective execution strategy. We develop a yearly business plan that acts as a roadmap to guide us toward our goals," he noted. "Managers and supervisors contribute their tactical ideas and identify needed resources. Our yearly business plan is a vital roadmap. It becomes the shared vision that aligns the entire integrated laboratory organization behind a common mission."

Voice Of The Customer

"SQL's entire execution plan is organized around the 'Voice of the Customer'," continued Dexter. "An employee incentive plan fuels the execution plan. Bonuses are linked to the achievement of each year's goals. All of our employees participate in the bonus plan and are required to receive mandatory annual training on quality, customer satisfaction, safety, and compliance. Employee retention and training are critical to a quality laboratory operation."

"The lynchpin of the Six Sigma quality improvement process is metrics," Dexter noted. "Within our lab, there are two guiding concepts. First, if you don't measure it, you can't manage it. Second, if you measure it, people are much more likely to do it."

Constant Measurements

"That is why we measure all work processes and outcomes. These metrics give timely and accurate guidance as we strive to achieve best practice and world-class performance for every function. To verify our metrics, we use internal and external audits," he said.

"When we audit our performance with customers, our primary Six Sigma quality improvement tool is the 'Voice of the Customer' survey," observed Joyce Santis, Chief of Operations at SQL. "We identify and sustain our quality standards based on these surveys."

"We survey customer satisfaction and patient satisfaction every quarter,"

added Santis. "Each year we survey all employees to measure how effective we are in terms of pay, perceived quality of our organization, and whether the employee has the tools and the authority needed to perform the job."

Last May, in a presentation at the *Executive War College* in New Orleans, Louisiana, Santis shared how SQL used quality management methods and employee surveys to effect far-reaching change. In 1999, the voluntary turnover rate was 38% and only 33% of employees completed the employee survey. As quality systems were deployed in the organization, this situation changed. By 2004, the voluntary turnover rate had shrunk to just 10.5% and 98.8% of the lab's 1,800 employees completed the employee survey.

Increasing Lab Value

"Six Sigma methodology provides a vehicle for remolding organizational culture and employee mindset, directly contributing to higher levels of service and customer satisfaction," stated Dexter. "Our roadmap to the Governor's Award positions us for pay-for-performance. We are using our quality initiative to increase the value of SQL's services to payers, physicians, and patients."

"For example, health insurers typically look at laboratory testing as a commodity," he continued. "Our strategy is to show insurers that we are not a commodity. Laboratory services carry a lot of value for insurers. With laboratory results impacting 70-80% of the diagnostic process, we offer tremendous value to our customers. We meet with each payer quarterly and present our metrics documenting our performance and improvement levels."

"Our total commitment to quality is a way to set ourselves apart from the competition," stated Jean Hammelev, Executive Director of Quality at SQL.

"We use customer satisfaction surveys to measure our competitive differential. Over the past five years our competitive differential has been extremely high. It lends significant credibility to our value proposition in the Arizona service market."

"The benefits of a total quality commitment strategy far outweigh the daunting challenges of implementing a quality improvement program," advised Dexter. "They include net cost reductions, better TAT, improved overall service quality, and a significant reduction in employee turnover."

"A program like Six Sigma is tough to implement," Dexter noted. "Every employee has to learn new ways to do things. There is always the temptation to go back to the old familiar way of doing things. This is where consistent, ongoing reinforcement from top-level management is critical. It essentially becomes a process of substituting 'work-around' for what works—at all levels. It reduces the overall complexity. As work processes become more efficient, they also become less stressful."

Going For The Baldrige

Where does a successful story like this one go from here? "We'll apply for the National Baldrige Award in 2007," stated Dexter. "Although, it might be a long shot, we have the outcomes and performance results to be a contender. Our strategy for continuing our quality improvement journey will include externally benchmarking against companies outside the laboratory industry. We will also try to give back to the quality movement by having even more employees at LSA/SQL become state and national quality award examiners." **TDR**

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

—By Pamela Scherer-McLeod

INTELLIGENCE

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



In Birmingham, England last week, **THE DARK REPORT** and the United Kingdom's **Association of Clinical Biochemists (ACB)** conducted the fourth annual "Frontiers in Laboratory Medicine" (FiLM) meeting, which showcases laboratory best practices in North America and the United Kingdom. At FiLM, it was suggested that lab directors and pathologists in the United States and Canada may be interested in attending next year's event and visiting several laboratories in England. Should any clients or readers be interested in traveling next February to England for FiLM and laboratory site visits, they should contact Robert Michel at labletter@aol.com. He will gauge interest and work to arrange such a tour.

XIFIN ADDS DIRECTOR

XIFIN, Inc. has added Judd Jessup to its board of directors. Jessup was CEO of **US LABS, Inc.** and helped sell it to **Laboratory Corporation of America** in early 2005. Located in San Diego, California, XIFIN offers laboratories an ASP-based system for accounts receivable and financial management.

EARLY-STAGE TEST FOR LUNG CANCER SHOWS PROMISE

Efforts to develop a blood test that can detect non-small cell lung cancer (NSCLC) in early stages is showing promise. In a few months, researchers at the **University of Kentucky** (UK) expect to present new data on this lab test to the **National Cancer Institute** (NCI) Early Detection Research Network. Edward Hirschowitz, M.D., Li Zhong, Ph.D., and their colleagues identified antibodies produced in response to lung cancer development. Studies conducted to date indicate a 90% ability to predict NSCLC, even in its earliest stages.

ADD TO: Lung Cancer Test

Market potential for this test is significant. About 172,000 new cases of lung cancer are diagnosed each year. Since most diagnoses are made later in the course of disease, lung cancer deaths total approximately 160,000 annually. Because NSCLC is involved in 80% of lung cancer cases, there would be strong interest in a

highly-sensitive blood test that can detect NSCLC in its early stages. In December, the University of Kentucky licensed exclusive rights to this test to **20/20 GeneSystems, Inc.**, a firm in Rockville, Maryland. The company says it will use its proprietary layered peptide array (LPA) platform and the UK team's biomarkers to create a screening test for the early detection of lung cancer.

OML ON THE MOVE

Oregon Medical Laboratories, Inc. (OML) is on the move—literally! Last month it moved into spacious new quarters, following a one-year build-out of a 70,000 square-foot lab facility. The new lab is located in Springfield, Oregon, a bedroom community for nearby Eugene. OML has installed an automated specimen processing system manufactured by **Probenverteiltechnik GmbH (PVK)**. It is the first lab in the United States to install one of PVK's automated systems.

*That's all the insider intelligence for this report.
Look for the next briefing on Monday, February 27, 2006.*

PREVIEW #2

EXECUTIVE WAR COLLEGE

May 3-4, 2006 • Intercontinental Hotel • Miami

Australia's Sonic Healthcare Ltd. and Its Global Laboratory Business Strategies

When Sonic Healthcare Ltd. acquired Austin, Texas-based Clinical Pathology Laboratories last summer, it marked the arrival of a new billion-dollar lab competitor in the United States. In an *Executive War College* exclusive, Sonic CEO Colin Goldschmidt, M.D. will provide attendees with a first-hand look at this international laboratory powerhouse. Sonic operates clinical laboratories in Australia, New Zealand, Germany, England, and the United States. In his first *War College* appearance since 2000, Dr. Goldschmidt will update the company's business strategies and its plans for the U.S.

Full program details available now!

visit www.darkreport.com

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- ***Peeking Behind the Biotech Curtain: New Diagnostic Technologies with Disruptive Potential for Both AP Groups and Clinical Labs.***

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