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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

Restricted information, see page 2

Commentary & Opinion by...

R. Lewis Dark

Founder & Publisher

Medicare's Lab Competitive Bidding Demonstration

EVERYONE SHOULD MARK JANUARY 1, 2007 ON THEIR CALENDARS. On that date, just 14 weeks from now, Medicare administrators intend to announce which laboratory bidders will be allowed to provide lab testing services in the laboratory competitive bidding demonstration that was mandated by the 2003 Medicare bill.

Never mind that officials at the **Centers for Medicare and Medicaid Services** (CMS) have yet to identify which region of the country will be involved in this demonstration project. Nor have they released information on how laboratories must respond, how "winning" bids will be selected, how laboratories exempted in the 2003 law will participate, and what type of appeals procedure will be available to non-winning laboratories that currently provide testing services in the region selected for the demonstration project.

Against this information vacuum, it seems that the next 14 weeks will be awfully busy—not just for some folks at CMS tasked with implementing the laboratory competitive bidding demonstration project, but also for the laboratories that find it is their service area which will be the demonstration site.

Oh, and there is something else you should know. Despite all the CMS fanfare and hoopla in the past couple of years that a panel of laboratory industry professionals will be meeting regularly to provide advice and input to CMS and its contractor on the best way to design and manage this demonstration project, not much has happened on that front. There's been no recent meetings of the lab advisory panel and, by all appearances, CMS and its contractors will go blithely down their own path in designing and implementing the Medicare laboratory competitive bidding demonstration.

Long-time clients and regular readers of THE DARK REPORT probably know how I feel about this situation. When it comes to laboratory contracting, federal and state healthcare adminstrators have an abysmal record. In fact, these pages have chronicled many of their lab contracting foibles in recent years. So I am not optimistic that the final design and execution of this laboratory competitive bidding demonstration will prove satisfactory to any stakeholder—and that certainly is likely to include the Medicare patients in whatever region is selected for the demonstration. TDR

Lab Competitive Bidding Project Slated For Jan. 1

Medicare officials have yet to disclose which regions and zip codes will be involved

CEO SUMMARY: In a rather quiet fashion, Medicare officials have disclosed timetable dates for implementing the laboratory competitive bidding demonstration mandated by the 2003 Medicare spending bill. Medicare intends to announce the names of participating laboratories by January 1, 2007. It also wants to implement demonstration pricing in the target regions by April 1, 2007.

IN JUST FOURTEEN WEEKS, the **Centers for Medicare and Medicaid Services** (CMS) plans to disclose the names of laboratories eligible to participate in the upcoming Medicare demonstration project for the competitive bidding of laboratory testing services.

By January 1, 2007, CMS intends to distribute to Medicare carriers the list of laboratories eligible to participate in the demonstration because of their bid. It is planning to implement the laboratory demonstration fee schedule by April 1, 2007.

These dates appeared in a document produced by CMS and dated July 28, 2006. It is titled "Subject: Laboratory Competitive Bidding Demonstration Project" in the CMS Manual System under "Pub 100-19 Demonstrations" (Transmittal 48, Change Request 5205).

The document lays out some procedures and steps to be taken to implement the Congressionally-mandated demonstration project. This project was authorized in the Medicare spending bill passed in 2003.

This news is likely to be a surprise to most pathologists and laboratory directors. CMS has made few public announcements about the laboratory competitive bidding demonstration project and has yet to disclose which regions of the United States will be involved in the demonstration.

Under this newly-disclosed timetable, CMS has little more than three months to announce the details of the

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bidding process, distribute forms to interested laboratories, hold public meetings on the specifics of the demonstration, accept bids, evaluate these bids, and designate which laboratories will participate in the demonstration.

One watchdog for the laboratory industry was first to get a copy of the July 28 CMS document and make its contents public. That was the **American Clinical Laboratory Association** (ACLA), based in Washington, DC. ACLA has closely tracked this demonstration project and the efforts by CMS and its contractors to establish the program parameters and implementation timetable.

"Given that laboratories do not know the demonstration site, the details of the design of the demonstration, or whether they will be required to bid," observed Alan Mertz, ACLA's Executive Director, "it's unrealistic to think that they will be able to prepare and submit bids for virtually all the tests on the clinical laboratory fee schedule, and that CMS will be able to evaluate the bids, determine the demonstration fee schedule, and select winning bidders, all by the end of the year."

Impending Train Wreck

THE DARK REPORT observes that the Medicare laboratory competitive bidding demonstration has all the characteristics of an impending bureaucratic train wreck. For starters, the Medicare program itself is a major source of distortions and inappropriate incentives within the American healthcare system. Critics of federal healthcare programs often characterize Medicare and Medicaid as operating like a Soviet-style bureaucracy, dictating prices and terms which are often disconnected from real costs and prices in the healthcare marketplace.

So, to embed a laboratory competitive bidding demonstration within the Medicare system means that this program starts from an unstable foundation.

Second, it is bureaucrats who must define the demonstration project and create a process by which this demonstration can be implemented. Although it is widely-recognized that most bureaucrats are well-meaning and want to do the right thing, experience teaches that the product of their effort is often unsatisfactory to consumers, industry participants, and Congress.

Discounted Pricing

There is another disturbing element to the laboratory competitive bidding demonstration. Although CMS named a panel of laboratory professionals specifically to offer advice and input, CMS has failed to utilize this panel. During the past 12 to 18 months, members of this panel have had minimal contact with CMS and its contractors. Thus, Medicare officials and their contractors are developing the demonstration policies and protocols without significant and timely input from the very panel of laboratory professionals selected for this purpose.

Moreover, this panel of laboratory professionals, if involved appropriately in the design and implementation of the demonstration, would have provided significant credibility for CMS. Given the implementation timetable described on July 28, it appears that CMS will proceed without this input and will be vulnerable to the inevitable criticism about flaws in the program's design and implementation.

This laboratory competitive demonstration project has the potential to do much harm to the existing resource base of clinical laboratories. It appears that the next 14 weeks will, by necessity, be very eventful for the laboratory industry. TDR

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Siemens' IVD Purchases Are a Major Investment

By acquiring DPC and Bayer Diagnostics, Siemens has triggered much speculation

***CEO SUMMARY:** In the space of just nine weeks, Siemens AG purchased Diagnostic Products Corp. (DPC) and Bayer Diagnostics. Siemens paid $1.86 billion and $5.31 billion, respectively, for the two* in vitro *diagnostics (IVD) companies. Once it closes the acquisition of Bayer Diagnostics, Siemens will have the third largest IVD business in the world. Experts predict more consolidation in the IVD industry.*

IF THERE WAS ANY SINGLE TOPIC that dominated conversations at last month's annual meeting of the **American Association of Clinical Chemistry** (AACC) in Chicago, it was about the upheaval that might result in the *in vitro* diagnostic industry as a result of **Siemens AG's** recent IVD buying spree.

On April 27, Siemens Medical Solutions announced that it would pay $1.86 billion to acquire **Diagnostic Products Corporation** (DPC), based in Los Angeles, California. That purchase was completed on June 28. *(See TDR, May 22, 2006.)*

One day later, on June 29, Siemens announced that it would pay $5.21 billion to acquire **Bayer Diagnostics** from **Bayer Healthcare AG**. Bayer Diagnostics had sales of approximately $1.8 billion during 2005.

With Siemens placing a major bet on *in vitro* diagnostics, Wall Street analysts predicted that Siemens' two largest competitors in imaging, **GE Healthcare** and **Philips Medical Systems**, would now be under pressure to do their own acquisitions of major IVD companies.

Given the ample war chests available to both companies, it meant that almost any IVD company could be a target of interest—if GE and Philips intend to match the strategic business moves of Siemens. Thus the rampant speculation around the AACC exhibit hall as to which IVD companies might be next in the ongoing consolidation of this lab industry segment.

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THE DARK REPORT believes the bigger story can be found in the motives of Siemens to spend more than $7 billion to buy a major presence in the IVD marketplace. Public statements by Siemens' executives consistently center around their intent to pursue specific strategic objectives.

"Demographic change is greatly increasing global demand for healthcare services and thereby generating excellent growth opportunities for Siemens," stated Dr. Klaus Kleinfeld, President and CEO of Siemens. With this statement, Kleinfeld describes Siemen's expectation that the aging baby boomer generation is going to fuel a steady increase in demand for diagnostic services.

Integration of Diagnostics

But it was Kleinfeld's next statement which is more telling. He then said "The acquisition of Bayer Diagnostics is part of our targeted strategy to create the healthcare industry's first integrated diagnostics company by combining the entire imaging diagnostics, laboratory diagnostics, and clinical IT value chain under one roof."

Siemen's grand vision is provide the healthcare system with an integrated diagnostics capability—one that includes imaging, *in vitro* diagnostics, and the information technology solutions necessary to support the clinician in making the right decision as early as possible.

In particular, Siemen's recognizes the potential of molecular technologies to do the following: 1) to identify the causes of diseases by genetic profiles; 2) to predict the effects of medications selected; 3) to tailor treatment for individual patients; and, 4) to diagnose disease at an early stage.

THE DARK REPORT believes that Siemens has a more sophisticated strategy for clinical diagnostics than most observers realize. The key words underpining this strategy are "presymptomatic diagnosis." Siemens wants to be first to have the ability to identify problems in a patient before any of the traditional symptoms can be seen.

Early Diagnosis Of Disease

In its public statements, Siemens generally describes this capability as the "ability to diagnose disease at an early stage." Erich R. Reinhardt, President and CEO of **Siemens Medical Solutions**, specifically said as much when he stated that Siemens views molecular medicine as having the proven potential to "isolate the molecular makeup of an illness long before a patient ever experiences outward signs of disease."

At the AACC meeting, Mohammed Naraghi, Siemens' Senior Vice President of Global Business Development, conducted a press briefing. In the audience was Bruce Friedman, M.D., Professor of Pathology at the **University of Michigan Medical School** in Ann Arbor, Michigan. Friedman, a recognized expert in laboratory informatics, observed that Naraghi's comments consistently centered around the company's goal of developing new technology in imaging and *in vitro* diagnostics that would bridge the gap between the two fields and achieve the ability to accurately make a presymptomatic diagnosis.

More IVD Consolidation?

So what does all this mean for pathologists and laboratory executives? In the short term, Siemen's willingness to spend billions to buy into IVD may indeed trigger a reaction from GE and Philips. That would mean further consolidation in the IVD marketplace.

In the long term, Siemens' $7.2 billion investment into *in vitro* diagnostics signals that laboratory testing is soon to achieve a higher profile within healthcare. That can only be positive for the laboratory profession. TDR

IVD Executive Discusses Three Developing Trends

Published interview describes existing flaws in analyzers, automation, and software

CEO SUMMARY: ***In a refreshingly candid assessment of current technology published in* IVD Technology *magazine, one lab industry executive describes both the successes and the failings of analyzers, automation, and software. He offers three trends he expects will address the deficiencies of the current generation of products. Help appears to be on the way, even if it will take a few years to reach the market.***

SERENDIPITY IS THE WORD that describes the unplanned and fortuitous conjunction of events. It aptly describes the May publication of an interview with a top executive at one of the leading IVD companies, discussing laboratory automation and lab software, even as early adopter laboratories at the *Executive War College* in Miami last month were sharing their lessons learned.

In the May 2006 issue of *IVD Technology* magazine, David P. Herzog, Ph.D., who is Senior Vice President, Instrument Systems Division at **Diagnostic Products Corporation** (DPC) in Los Angeles, California, wrote a story in which he described "three emerging trends that may improve automation and take lab efficiency to the next level."

THE DARK REPORT now offers an edited selection of his specific comments on the problems caused by today's level of instrument, automation, and software technologies. It confirms the assessments presented in June 12, 2006 issue of THE DARK REPORT, and adds understanding to the reasons why many forward-looking laboratories are implementing pieces of automation, looking for third-party middleware sources, and deploying quality management methods in their laboratories.

Today's Large Analyzers

Early in his story, Herzog addresses the problems of today's large analyzers and instrument systems. Herzog recognizes that IVD (*in vitro* diagnostics) manufacturers have designed their products to save labor. He writes, "By looking for solutions to minimize labor further, today's total lab automation (TLA) systems integrate multiple analyzers, automate specimen preparation, and facilitate sample retrieval when additional testing is required.

"The resulting systems often require labs to spend more than $1 million on complex, rigid automation systems to achieve the much needed productivity improvements. Manufacturers are reaching the limits of current analysis technologies as high-volume instruments become too large to fit into some labs.

"In addition, the growth in complexity and physical size of analyzers and automation systems has required IVD manufacturers to design higher levels of embedded instrument intelligence for performance monitoring. Many analyzers contain sophisticated sensors and software that manage every step of sample processing, ensuring that it is carried out with quality and precision. Such systems give labs and manufacturers new opportunities to access a wealth of real-time sample and instrument data that the automation software may use to efficiently manage the testing process."

Describing Some Problems

Following this summary of the current state of IVD technology, Herzog then describes some of the problems, many of which will be familiar to clients and regular readers of THE DARK REPORT. (The use of italics in Herzog's statements is done by us to draw emphasis to certain points.)

Herzog describes several problems, saying, "However, due to legacy systems and limited efforts in system integration, *most of the automation software on the market today is complex and difficult to use*. Lab technologists must use multiple screens and workstations to access test and instrument data. *Software commands are complex and multi-step, even for the basic lab processes* such as the review and release of test results. While today's analyzers can deliver growing amounts of real-time instrument and test data, *automation software has not caught up to translate data into effective lab management tools*.

"Instrumentation bloat and software complexity have limited the gains that labs have seen from automation," he wrote. "These issues, though, are undergoing change."

Herzog has more to say on the subject of software, "*Automation software limitations slow down lab processes* and do not allow labs to realize the analyzer's test volume potential. For example, automation software that does not allow any test results to be released until the slowest test has been completed limits productivity gains from a multi-million-dollar investment. Staff savings are constrained by software that requires lab personnel to walk around the lab and view screens on multiple workstations in order to manage an automation system.

"Instrumentation bloat and software complexity have limited the gains that labs have seen from automation," he wrote. "These issues, though, are undergoing change."

"The next generation of lab automation software will move away from today's fragmented, complex systems by integrating all aspects of lab management, from sample logistics to results management, archiving, and retrieval. Access to the laboratory information system (LIS) and all lab processes will go through a centralized control function. Labs will achieve productivity gains by consolidating data and instrument management, and not requiring lab personnel to monitor and manage various data feeds on multiple screens. This emerging functionality may enable a staff of fewer than five technologists to manage a lab delivering millions of tests per year.

Demand For Solutions

"Laboratory demands will drive this software trend. *Lab managers and their personnel are increasingly frustrated by automation software that has not caught up with the capabilities of the analyzers, and cannot provide*

access to and management of the lab data. A survey by Diagnostic Products Corp. (DPC) found that many labs believe their automation software is several generations behind the functionality of the instruments."

Herzog summarizes his view by predicting three trends which, as he puts it, "will drive laboratory automation's future." First will be "smaller, more flexible analyzers and automation based on next-generation technologies, including microfluidics."

Herzog foresees that developing microtechnologies will create smaller instruments, which use smaller amounts of sample (he predicts 100 nl–50 µl), as well as reagents.

The second trend identified by Herzog is "easy-to-use, powerful software for centralized lab management." After noting that, in today's laboratory, techs must view multiple screens on multiple workstations around the laboratory in order to manage the automated system, Herzog observes that the solution will be in simple-to-use software that integrates and controls all the management functions, and can be accessed from any single workstation in the laboratory.

The third trend reflects the IVD executive's enthusiasm for the potential of developing technologies to address the QA/QC challenges resulting from today's "big box," high-volume automated systems. Herzog predicts that "Internet-based real-time service for better uptime" performance of the laboratory's instrument systems will become common.

Remote Monitoring Via Web

He explains that IVD manufacturers are learning how to tap into the "analyzer's built-in intelligence to monitor and diagnose instruments remotely," including via the Web. Not only can this allow the vendor to spot impending failures of the analyzer's parts and systems, but it opens the door to added value services.

In particular, Herzog notes that DPC is already using Internet connections with its installed analyzers to collect quality control information and provide this information back to the laboratories. With enthusiasm, he notes that, "This technology can generate quality control reports for the labs in real time and can download composite peer information to a Web browser at any time, anywhere in the world. Labs will no longer need to wait for the next monthly summary of quality control results to find out how their performance compares with their peers."

Herzog's comments show that the IVD industry recognizes that, in creating large, high-volume analzyers and automated systems, it has contributed to increased labor productivity in laboratories. At the same time, Herzog offers candid comments on the weaknesses of these systems and the operational problems they create for laboratories.

Unlocking Productivity

This is why THE DARK REPORT has repeatedly pointed out that, even as laboratories enjoy the benefits that accrue from using some of these large analyzers and automation solutions, they still have a compelling need to continuously attack existing bottlenecks and unlock additional productivity gains.

Progressive labs are emphasizing operational efficiency. They are redesigning deficient or inadequate work processes in pre-analytical, analytical, and post-analytical work flow. Middleware and quality management methods are proving to be effective tools to accomplish these goals. TDR

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CEO SUMMARY: Since October 2003, the core laboratory of Detroit Medical Center University Laboratories has operated with a home-grown total laboratory automation (TLA) system. The 100-foot automated line currently connects to 11 instruments and the hardware cost only $200,000 to build and install. Not only did it allow 20 medical technologists to shift to other positions within the laboratory, but this automated line has operated 24/7 for almost three years without a major stoppage.

DEVELOPED AT DETROIT MEDICAL CENTER

Pathologist-Entrepreneurs Offer New Lab Automation

IN AMERICA, THERE IS A GREAT TRADITION of someone who gets the "better idea," begin to tinker in his garage and evenutally emerges with useful new products that find rapid acceptance in the marketplace.

The first two statements above aptly describe the activities of pathologist William Neeley, M.D., FCAP, DABCC and his colleagues at the **Detroit Medical Center-University Laboratories** (DMCUL) in Detroit, Michigan. For the past three years, they have operated a homegrown system for total laboratory automation (TLA) in the DMC core lab.

Now these pathologists are taking the next big step. They have launched a company to sell this automation solution to other laboratories. Under the name **Integrated Laboratory Automation Solutions, Inc.** (iLAS), based in Troy, Michigan, Neeley and his colleagues are prepared to sell what they describe as an "innovative, reliable, and cost-effective system of laboratory automation."

Operational Since 2003

The iLAS automation system has operated at DMCUL since October 2003. "In almost three full years of 24/7 operation in a laboratory that performs more than 10 million billable tests per year, there has never been a significant stoppage of the automated line," observed Neeley. "That speaks to the robust performance of this automated system.

"Simplicity, ease of operation, and reliability were intentionally engineered into our automation," stated John Crissman, M.D, President and CEO of iLAS and former Chairman and Dean of the **Wayne State University School of Medicine**. "It is a flexible system. Any laboratory instrument with the capability to interact with automation can be connected to our automated line."

The DMCUL core lab serves a consolidated laboratory system that includes eight hospitals, as well as physician office laboratories. When Neeley, Crissman, and fellow pathologist David Grignon, M.D, (who is an iLAS officer and current Professor and Chairman of the Department of Pathology at Wayne State University) decided to develop their own automation system, they already had an earlier automation template to draw upon. In the 1990s, Neeley had developed an effective, custom-built automation system at **Meris Laboratories, Inc.**, located in San Jose, California.

With a capital expenditure of around $75,000, Neeley had used a standard commercial conveyor belt and off-the shelf bar code readers. this hardware was married to a custom software code that his lab team created. The combination produced a remarkably simple and effective automation system at Meris. THE DARK REPORT was first in the nation to describe this development to the lab industry. *(See TDR, August 2, 1996.)*

Lessons Learned

"Before you ask, yes, I did apply the lessons learned from that automation solution to the design and operation of our current system here at Detroit Medical Center," noted Neeley. "It is important for other laboratorians to understand what we did here. This system is designed around a few basic objectives.

"First is reliability," he said. "We wanted an automated line that would perform tirelessly without malfunctions and equipment failures. That's essential in a laboratory performing 10 million billable tests per year.

"Second is simplicity. Automation must be easy for the lab staff to understand and to operate," added Neeley. "Laboratory staff should find it intuitive and adaptable to what is needed to support the actual analytical process.

"We addressed simplicity in two ways," he continued. "All hardware was made from standard, off-the-shelf industrial components. That makes it easy and fast to replace any part. Moreover, because these are standard components, their reliability is incredible. In our three years of operation, the automated line has never broken down and the

Pathologists Trained In Engineering

TWO OF THE THREE PATHOLOGISTS involved in the founding of Integrated Laboratory Automation Solutions, Inc. of Troy, Michigan completed training in engineering courses.

John Crissman, M.D. completed his undergraduate degree in mechanical engineering. William Neeley, M.D., upon his graduation from medical school, completed coursework in electrical engineering.

Both pathologists say that this engineering background was invaluable in helping them design a total laboratory automation (TLA) system that incorporated off-the-shelf industrial components, met the functional needs of the laboratory, and operated in a simple, straightforward manner.

In another coincidence, both Crissman and Neeley served as residents together. They did their residency at the Institute of Pathology at **Case Western University Medical School** in Cleveland, Ohio.

only component failure that we had was a small sensor that died a natural death after several years of 24/7 operation.

"The other element used to simplify our automation is software," said Neeley. "We wrote code designed specifically to meet all the needs of a clinical lab. It is software for labs, written by lab people. That means it has *all* the functions and options that you've always wanted in your lab, but could never get from a commercially-developed lab software product.

"Third, our automation is designed to hook up to almost any laboratory instrument," he observed. "This is truly the open system that laboratories want. If the instrument has the capability to connect to automation, it can operate with our automation solution.

"Fourth, this automated line is modular. The basic module can connect as few as two or three instruments. The laboratory can add automation modules as needed to the line," Neeley noted. "In our laboratory, we currently use a 100-foot automated line that connects 11 instruments.

Effective Software

"Fifth, we consider software to be our secret to success. As working laboratorians, we designed our automation software to expressly meet all the needs in our laboratory," he said. "The software is compatible with autoverification software sold by many vendors so that labs can gain maximum efficiency from this automation system."

"Sixth, our system is intentionally designed to handle all types and sizes of tubes," continued Neeley. "For us to be competitive in the laboratory outreach market—which is 48% of our volume—we want to accept multiple sizes and types of tubes and be able to run them as primary tubes through our automation."

The desire to use primary tube sampling reveals some of the inspired genius in Neeley's thinking about laboratory automation. "In our laboratory, the philosophy is we will accept any tube submitted and run that tube as the primary specimen through our laboratory. That generates huge labor and cost savings even as it often contributes to a better quality specimen," explained Neeley.

Running Short Specimens

"This also touches upon one aspect of lab automation that is seldom discussed," continued Neeley. "In most automated labs, a short specimen can't be run on the line. Manual labor is required to correct the situation and that drives up the ongoing cost to run that automated line.

"This is not a small problem," he added. "Up to 20% of our tubes are short draws. Our solution is pour the specimen in a cup and drop that cup in the primary tube so that instrument probes can sample from that specimen as it moves down the line."

THE DARK REPORT has done a site visit to the DMCUL core laboratory and watched how this custom-designed automation solution works in actual operation. It has an economical footprint and the flexibility to add or subtract modules without major construction or renovation costs.

One impressive feature about this automation was its very low cost. "To install the track and hook up 11 instruments, we spent about $200,000 on hardware," stated Crissman. "Software costs were additional. But the total was only about 25% of what a lab must normally pay. However because the system is tailored to our laboratory's unique needs, we've seen substantial gains in productivity and functionality. In fact, we got payback from our automation in about six months!

20 Fewer MTs Needed

"For example, our high volume core lab now operates with 20 fewer medical technologists (MTs)," he explained. "We shifted these MTs to other areas of the laboratory where they do value-added work.

"Our automated line is also designed to accommodate STAT tests and respond to any work flow issue," Crissman noted. "The software directs STAT tests to specific instruments that have the shortest queue. That means our MTs don't have to manually handle STAT tubes."

"Another thing our software does is constantly monitor all the functions along the automated line," interjected Neeley. "If it determines there is a problem, it will automatically re-route affected tubes. There are two different scenarios for this function.

"The first deals with non-functioning instruments," continued Neeley. "Because of our large sample volume, we have at least two or more identical instruments on the system. If one instrument fails, the software will automatically route samples to the other instrument and a flashing light will provide a visible alert that something is wrong with the instrument. The instrument may have failed or is about to run out of a reagent.

"The second scenario is when all the same type of instruments fail at the same time," he explained. "Our software automatically routes affected samples to an aliquot or holding station. Here they are racked and can be easily routed to the instruments once they are returned to service. Otherwise, in many other automated systems, the samples will be placed in storage and a significant amount of labor would be required to locate and retrieve those samples.

"This has proved to be particularly useful when an instrument ceases to function," stated Neeley. "The software automatically identifies that situation and re-routes affected tubes to the holding station. This feature has radically cut down on misdirected specimens.

"Further, we have a different philosophy about aliquoting," observed Neeley. "To the maximum extent possible, we use primary tubes. In my view, aliquoting creates multiple 'dead' specimens and increases labeling and tube identification problems, as well as the incidence of running out of samples.

Primary Tube Labels

"Since we rely on the label of the primary tube, we avoid the problems of some automation solutions, which may track a tube by the rack number which carries it," he offered. "Whenever rack and tube become separated without the lab automation recognizing this fact, it creates the opportunity for a lost tube or sample identification errors and the resulting confusion. Our reliance on primary tubes and the single label contributes to the sustained high performance of this automated system."

During the past four years, Neeley has appeared at several laboratory meetings, including the *Executive War College on Laboratory and Pathology Management*, to discuss the automation effort underway at Detroit Medical Center University Laboratories. His thinking on automation was prominently featured in *CAP Today* Magazine in August 2002.

Encouraging Response

"It was the feedback and positive reaction from other pathologists and laboratory directors that motivated us to offer this laboratory automation solution," commented Neeley. "We are convinced that one reason why TLA has not found wider acceptance is because early generations of this product failed to meet both the needs and the expectations of many laboratories."

"That is not the case at DMCUL, where this customized laboratory automation system has performed without major interruption in a high-volume core laboratory on a 24/7 basis for almost three years," said Crissman. "It has generated substantial increases in productivity—at an extremely low cost. Its customized and flexible design supports our operational needs, as well as ongoing work flow redesign.

Raising Lab Performance

"These are all reasons why we believe that other laboratories will be interested in learning how they can use this lab automation system to achieve similar benefits," added Crissman. "We are working pathologists and have created a TLA system that helps other pathologists and lab directors raise the performance of their laboratory operations."

Crissman, Neeley, and Grignon are the newest entrepreneurs in the pathology profession. Although they are enthusiastic about the prospects for selling their automation solution to other laboratories, they also recognize the challenges. "We understand our place in the market," said Neeley. "Our contribution to the laboratory is to simply provide tube transport and to not compete with instrument vendors.

"To achieve this, our automation system can readily connect to a host of analyzers," he continued. "It is modular, handles a variety of tube sizes, and both the hardware and software can be quickly customized to our laboratory customer's unique needs."

"Best of all," added Crissman," is the fact that almost any laboratory can acquire this system at a rock-bottom cost. We estimate that a smaller laboratory can automate and connect between one and three analyzers for as low as $100,000. To do a system comparable to DMCUL, with up to 13 instruments, the total cost would run about $500,000."

No Misconceptions

Crissman, Neeley, and Grignon have no misconceptions about the business challenge that awaits them. Pathologists and laboratorians are skeptical about new technology and new companies, and that is certain to be true about a young company offering a new automation system.

"With the three-year track record of this system in the Detroit Medical Center University Laboratory, we know we have a credible product," predicted Crissman. "Because we can sell it at a price that is substantially below other automation options, we are hopeful that the combination will encourage interested laboratories to come by and 'kick our tires.' Moreover, it is likely that our first customer will get the deal of a lifetime, since we'd like to see this system in operation at other laboratories around the country." TDR

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10 Principles of Laboratory Automation As Developed by William Neeley, M.D.

"CLINICAL PATHOLOGY IS MY PASSION. From the time I left medical school, I have spent my time in the clinical laboratory, working to improve the quality of test results and streamline work processes in the laboratory," stated William Neeley, Medical Director of Labs at Detroit Medical Center University Laboratories in Detroit, Michigan.

In visits to laboratories under Neeley's direction over the past 10 years, THE DARK REPORT has developed a list of 10 critical parameters that Neeley uses when he develops an automated work flow solution for his laboratory. In some ways, Neeley's lab automation imperatives fly in the face of popular wisdom. But too often, it is this willingness to buck the popular wisdom that allows innovators to achieve a higher level of performance.

The following list of items is titled "William Neeley, M.D.'s 10 Precepts of Laboratory Automation" and represents our attempt to articulate the specific problem-solving strategies Neeley uses to create a reliable, effective, and low-cost total lab automation solution.

▶ William Neeley, M.D.'s 10 Precepts of Lab Automation

1. **SIMPLIFY ALWAYS, AT LOWEST COST—**Automation, in its best configuration, should serve the primary needs of the laboratory. Avoid solutions which require work-arounds or alterations of "common sense" work flow. Avoid complexity.
2. **EMPHASIZE RANDOM ACCESS AND RANDOM SPECIMEN—**Establish a work flow that incorporates analyzers capable of random access and different specimen types. Make this flexibility serve improved work flow through the laboratory.
3. **RUN TESTS IN REAL TIME, MINIMIZE BATCH TESTING**—This improves quality, speeds time to result and evens out work load on the instruments (which reduces the need for analyzers with a higher throughput).
4. **AVOID SECONDARY IDENTIFICATION LABELS ON THE TUBE—**Maximize how the laboratory uses the primary label on the tube, from pre-analytical to analytical and post-analytical.
5. **EMPHASIZE PRIMARY TUBE TESTING AND ALIQUOT AFTER CHEMISTRY AND IMMUNOCHEMISTRY TESTING—**Minimize the need to create aliquots by running primary tubes through as many analyzers as possible before creating aliquots of the specimen.
6. **AUTOVERIFICATION IS ABSOLUTELY ESSENTIAL—**This greatly decreases labor and allows medical technologists (MTs) to focus on problems and value-added tasks, while avoiding countless MT hours spent looking at thousands of unremarkable results.
7. **BE CAPABLE OF HANDLING MULTIPLE TUBE TYPES AND SIZES—**Saves ongoing labor needed to handle the specimens. Particularly important for laboratories in the outreach business that want to compete on both service and lower cost.
8. **STRIVE ALWAYS FOR THE LOWEST COST—**And remember that few vendors will offer the most cost-effective answer to the need.
9. **REDUCE COMPLEXITY—**Simplify at every opportunity. Try to use "off the shelf" solutions in software and equipment whenever possible.
10. **USE MIDDLEWARE TO GUIDE WORKFLOW—**Be creative and use middleware whenever it can simplify processes. Use it to direct automation and to support lab staff.

Supremes Rule Against LabCorp On Test Patent

One barrister believes there's good news in the dissenting opinion of three justices

CEO SUMMARY: It's a bad news/good news outcome for pathologists and lab administrators hoping for clearer guidance on patents granted for DNA and other diagnostic technology. The bad news is that LabCorp gets no relief from lower court rulings that it infringed patents on homocysteine testing. The good news is that three justices wanted to rule in this case, and likely in favor of LabCorp.

BY DECIDING NOT TO ISSUE a ruling in the case of **Laboratory Corporation of America Holdings** versus **Metabolite Laboratories, Inc.**, the Supreme Court of the United States effectively ruled against LabCorp. The Justices announced this action on June 22, 2006.

For clinical laboratories and anatomic pathology group practices, the lack of a definitive ruling means that the status quo in patent protection for many molecular tests and other medical processes is allowed to stand. However, some legal experts consider the willingness of the Supreme Court to consider LabCorp's appeal as a sign that the justices are looking for an opportunity to review current patent law with a thought to changing how patents are currently granted.

"LabCorp was appealing lower lower court decisions against it in a civil case involving patent infringement," stated David B. Cupar, an attorney with **McDonald, Hopkins** of Cleveland, Ohio. Cupar specializes in intellectual property rights, with a particular expertise in biotech and diagnostic patent law. "This case was high-profile because of expectations that the Supreme Court was about to issue a ruling that would affect patents granted for medical processes, DNA and molecular applications, as well as business methods."

Losses In Lower Courts

Lower courts had ruled that LabCorp, by performing homocysteine assays without paying royalties to Metabolite Laboratories, had infringed the patent held by Metabolite Labs. That patent is No. 4,940,658. It covers determination of a deficiency of folic acid (B-12) by measuring the quantity of the amino acid homocysteine in a patient's blood or urine. Over the past 10 years, the volume of homocysteine testing has increased steadily, as clinical studies offered evidence that high levels of homocysteine correlate to a higher risk of stroke or heart attack.

In 1998, LabCorp ceased paying royalties to Metabolite and Metabolite sued. LabCorp lost the civil case and was ordered to pay $5 million.

Homocysteine Tests Covered Under Patent Granted For Determining Folic Acid Deficiency

MANY PATHOLOGISTS AND LAB DIRECTORS are familiar with the patent that is connected with homocysteine testing. That's because the patent holder, in 2004, sent "royalty demand" letters to many hospital-based and independent laboratories in the United States.

First reported by THE DARK REPORT, in the fall of 2004, **Competitive Technologies, Inc. (CTI)** sent letters to many laboratories in the United States. The letter requested those labs which had performed homocysteine tests since January 1, 1998 to pay a $30,000 licensing fee and royalties of $1.83 per test sold by the lab since that date. That was CTI's estimate of a 6% royalty on the patient list price charged by laboratories. *(See TDR, November 1, 2006.)*

Competitive Technologies holds the assay patent on behalf of the **University of Colorado** (developers Robert H. Allen, M.D. and Sally Stabler, M.D.) and **Columbia University** (developer John Lindenbaum, M.D.—died 1997.) The University of Colorado owns Metabolite Laboratories, Inc., which was organized to develop uses of the patented technology.

U.S. Patent No. 4,940,658 ('658) is a two step method. First, the level of homocysteine is measured in a patient's blood or urine. Second, if elevated, that level can be correlated with a deficiency of folic acid (B12). It was developed in research to benefit patients with sickle cell anemia and vitamin B-12 deficiency, among other diseases.

The Supreme Court was facing a fundamental question: could a doctor infringe the patent "merely by thinking about the relationship" between homocysteine levels and B vitamin deficiencies after looking at a test result. LabCorp and its supporters argue that this is a basic scientific principle or natural phenomenon. It should not be patentable.

"If someone observes a correlation between X and Y and then announces he is going to use that correlation in a lab test, is that a patentable process? I think the court is troubled that this sort of correlation would be possible," stated Jack Beirig, a Chicago-based attorney with **Sidley Austin LLP.** Beirig filed a friend-of-the-court brief supporting LabCorp on behalf of the **American Medical Association** and five other medical associations.

On appeal, it lost again. It was ordered to pay the settlement and was also enjoined from performing homocysteine tests. *(See TDR, November 1, 2004.)*

"There was keen interest in this case because it centers around the key question of patents that are issued for scientific processes," observed Cupar. "For example, is DNA patentable? This question has been argued in courts since the early 1980s and the LabCorp case had many scientific parameters common to earlier cases on this subject."

Pathologists and laboratory administrators are all too familiar with patents covering scientific processes. Many molecular assays are protected by specific patents. Laboratory budgets are stretched thin by the need to pay royalties to the holders of these patents. **Roche's** patents involving polymerase chain reaction (PCR) are probably the best known example.

Dismissal Is Rare Action

"In dismissing the LabCorp case without a decision, the Supreme Court took a rare action," noted Cupar. "That's because it had agreed to hear the case,

then accepted written briefs and heard oral arguments. Why go this far, then decline to rule?

"I believe that, after studying the facts and arguments, the justices came to realize this was not the best case for them to use in establishing new legal precedents," explained Cupar. "Since the early 1980s, when the first patents were granted for DNA and some basic scientific processes, a steady flow of cases has been filed to challenge the validity of these patents.

"Thus, this type of issue has been in front of the court several times in the past 25 years," he added. "The LabCorp case has many of the scientific parameters that are common with earlier cases. That's probably why the justices were originally interested in hearing LabCorp's appeal of the lower court rulings against it."

"For the clinical laboratory profession, I see some good news in this situation, despite the Supreme Court's dismissal of LabCorp's appeal" noted Cupar. "First, the fact that the Court did agree to accept this case is a strong signal that it recognizes the need to bring more legal clarity to the patent issues involving genetics and bioscience.

Dissent By Three Justices

"Second, even though the case was dismissed with a one-sentence statement, three justices dissented in the dismissal action," he continued. "Justices Breyer, Suter, and Stevens issued a dissenting opinion. In it, they said, point blank, that the Metabolite Labs' patent is invalid because it covers a natural phenomenon.

"In particular, Justice Breyer, who wrote the opinion for the three dissenting judges, leaves an open door for LabCorp," said Cupar. "He points out that, in the lower court actions, LabCorp did not make reference to §101 of the Patent Act, which addresses the 'law of nature' principle which is to guide the issuance of patents. Justice Breyer then observes that the higher court would 'benefit from the views of the Federal Circuit, which did not directly consider the question.'

Door Open For LabCorp?

"This seems like an invitation to LabCorp to revisit the lower court and raise this specific question," he added. "It remains to be seen how LabCorp will respond to this development."

Cupar believes that the response of the dissenting justices to the LabCorp v. Metabolite case makes it inevitable that similar cases will find their way into the Supreme Court. "There is a silver lining in the refusal of the Court to decide this case," he stated. "Breyer indicates, in his dissent, that LabCorp might have prevailed had it raised the §101 Patent Act 'law of nature' principle earlier in its arguments. That's encouragement for other laboratories to litigate over patents deemed to involve a 'law of nature' process and defend their action with §101 of the Patent Act."

Cupar believes that all laboratories and pathology groups must stay alert to issues triggered by patents affecting laboratory tests. He recommends that pathologists and laboratory directors develop two types of strategies to protect themselves from patent and intellectual property issues.

Defensive and Offensive

The first patent-protection strategy is defensive. The second is offensive. THE DARK REPORT has asked Cupar to address each of these strategies in detail. His recommendations and insights on how laboratories and pathology groups should protect themselves from patent royalty claims will be presented in coming issues. TDR

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INTELLIGENCE LATE & LATENT

Items too late to print, too early to report

Here's some useful information for pathologists and practice administrators trying to gauge the interest that urologists, gastroenterologists, and dermatologists have in capturing the anatomic pathology revenues generated by their patient referrals (the TC/PC trend). **Pathology Service Associates** of Florence, South Carolina recently conducted a Web survey on this topic. 32% of the respondents said that local referring clinician specialists had approached their group asking for help to establish their own pathology laboratory (55 of 172 respondents). 28% said that local clinician specialists had asked for help to establish in-office pathology services (49 of 172 respondents).

MORE ON: TC/PC TREND

This is anecdotal evidence that a substantial proportion of specialist physicians are actively seeking ways to profit from their anatomic pathology referrals. Pathologists interested in contributing to the survey can visit *http://tellpsa.psapath.com/Survey1.aspx?SurveyID=0611816589&SGID=24&PNo=1.*

LUNG CANCER TEST PREDICTS LIKELIHOOD OF RECURRENCE

It's another step forward in the march toward personalized medicine. Researchers at **Duke University Medical Center** in Durham, North Carolina, have developed a molecular test to predict which early-stage lung cancer patients are at risk for a recurrence. "Using the unique genomic signatures from each tumor, our new test predicted, with up to 90% accuracy, which early-stage lung cancer patients would suffer a recurrence of their cancer and which patients would not," said Anil Potti, M.D., Assistant Professor of Medicine and a leader in the research project. "We now have a tool that can be used to move these high-risk patients from the 'no chemotherapy' group into the aggressive treatment group."

ADD TO: Cancer Test

The test is the "Lung Metagene Predictor." Researchers identified gene-expression profiles that predicted who, in a group of 89 patients with early stage NSCLC, had a higher risk of recurrence. Researchers then validated the test by looking at a group of 134 lung cancer patients. Next step in the development of this test will be a clinical study that enrolls up to 1,000 people from sites in the United States and Canada.

TRANSITIONS

• Effective today, Rick Panning assumes his duties as the new CEO of the **American Red Cross Blood Bank–North Central Blood Services Region**, based in St. Paul, Minnesota. Panning was formerly President, Laboratory services at **Fairview Health Services**, located in Minneapolis, Minnesota. While at Fairview, Panning was one of the first three laboratory administrators in the nation to formally introduce Lean and Six Sigma management systems into the high-volume core laboratories of several hospitals at Fairview Health.

• On Friday, August 4, Marie Cato retired from her duties at **ACL Laboratories** in West Allis, Wisconsin. Cato had been Director of Operations at the laboratory, which is jointly owned and operated by **Aurora Health Care, Inc.** and **Advocate Health and Hospitals Corporation**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, September 4, 2006.