Volume XI, Number 12 Monday, August 30, 2004

*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**

## *Raising the Bar on Laboratory Management Skills*

HURRICANE CHARLEY'S IMPACT ON LABS IN FLORIDA and Lean/Six Sigma's contribution to big improvements at **Mayo Clinic Scottsdale's** hospital laboratory provide powerful evidence that the science and art of laboratory management in the United States is reaching ever-higher levels. That's good news for our industry's management innovators. It's bad news for lab directors and managers at any level who are mired in the mindset of "status quo is just fine—my laboratory doesn't need to change!"

Continency planning and emergency preparedness were on display earlier this month when Hurricane Charley, blowing at sustained winds of 145 m.p.h., slammed into the west coast of Florida and blew its way up and across the peninsula. As you will read on pages 2-4, hospital laboratories in the region were ready. THE DARK REPORT can find no instance of a hospital laboratory failing to meet its service expectations and commitments. That is a remarkable accomplishment for our profession. It speaks to the quality of management leadership and to the character and integrity of all who work within the nation's laboratories.

Our contribution is to track down useful stories of how lab managers in Florida coped with the unexpected and unplanned. I'll bet many labs don't have a plan to communicate with employees at their homes who may lack power and telephones, even weeks after a regional disaster. That's just one of the lab management insights we share with you in this issue.

Turning to the cutting edge of lab management, laboratory leaders at Mayo Clinic Scottsdale Hospital had the vision, the courage, and the drive to be first, to our knowledge, to launch and complete a comprehensive Lean and Six Sigma quality management project within the Mayo organization. This demonstrates the influence that just one laboratory administrator can have when he/she sees the right thing to do, sells it to administration, then brings in the resources necessary to achieve ambitious goals.

Collectively, these examples demonstrate that laboratory management professionals are actively meeting all the challenges to be found in today's healthcare system. It is compelling evidence that the best management innovators in our profession are improving their skills and abilities. That raises the bar for the rest of us. TDR

# Florida Labs Face Off With Hurricane Charley

## *Contingency plans put to the test, emergency teaches new lessons*

***CEO SUMMARY: Hurricane Charley not only validated long-standing laboratory emergency contingency plans, but it introduced new issues. Even two weeks after the hurricane, hospital labs in the most affected communities continue to deal with storm-related problems. One issue is that damaged physicians' offices are closed, making it a challenge to report lab test results on patients who visit the ER.***

WHEN HURRICANE CHARLEY blew into Florida on Friday, August 13, it significantly damaged hospitals located dead-center on its storm track.

Laboratories in these hospitals, already operating in an emergency mode, found themselves challenged in several unexpected ways. New lessons in crisis planning for laboratory testing services emerged from their experience.

Hurricane Charley was a Category 4 storm. When it hit the west coast of Florida, it was packing sustained winds of 145 m.p.h. and the storm surge was 13 to 15 feet. The eye passed over Punta Gorda and Port Charlotte. These cities suffered the worst damage.

Charley moved northeast across Florida, losing strength as it went. Still, sustained winds of 105 m.p.h. were recorded in Orlando. Storm damaged lessened the longer Hurricane Charley moved across Florida.

All three hospitals in Punta Gorda were significantly affected by high winds and the power outage. **Charlotte Regional Medical Center**, F**awcett Memorial Hospital**, and **Bon Secours-St. Joseph Hospital** all had varying degrees of damage.

Hardest hit was Charlotte Regional Medical Center (CRMC). Windows were blown out in gusts that topped 175 m.p.h. Officials closed the hospital, except for the emergency room and patients were evacuated to other hospitals after Hurricane Charley passed.

In anticipation of potential coastal flooding, the laboratory at CRMC



THE DARK REPORT Intelligence Briefings for Laboratory CEOs, COOs, CFOs, and Pathologists are sent 17 times per year by The Dark Group, Inc., 21806 Briarcliff Drive, Spicewood, Texas, 78669, Voice 1.800.560.6363, Fax 512.264.0969. **(ISSN 1097-2919.)**

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established a temporary laboratory on the second floor of the hospital prior to Charley's arrival. This lab could do basic chemistry, hematology, electrolytes, urinalysis, and similar tests.

## Full Service Maintained

Generator power cut in when power lines failed and the lab told THE DARK REPORT that the planned level of lab test services was continuously maintained. Full clinical services were restored at the hospital on Monday, August 30.

Inland from Punta Gorda, the town of Arcadia took a beating from Hurricane Charley. **DeSoto Memorial Hospital**, a 49-bed facility, took minimal damage and was used by the **Federal Emergency Management Agency** (FEMA) as a medical emergency resource.

"Our laboratory infrastructure was not damaged," stated Julie West, Administrative Laboratory Director at DeSoto Memorial Hospital (DMH). "We implemented our contingency plan. Everything stayed up during the storm and the cut-over to power generators was accomplished without incident.

"With some water leakage into the building, we were forced to move special chemistry into my office," she noted, "but there was little disruption to our planned level of testing."

## Lab Lessons Learned

Several lessons were learned during the hurricane emergency at DMH. "While the storm was overhead, water was coming into the building and getting into the air conditioning ducts. This would set off fire alarms located in the ducts," stated West. "The lab is responsible for checking fire alarms during these types of crises. So, about every five minutes during the hurricane, another alarm would go off and lab staff would need to go check that location. This was a necessary, but unwelcome distraction, during that time."

FEMA's presence in Arcadia was immediate. "Two med techs from the **Miami VA Medical Center** were assigned to us the day of the hurricane," explained West. "They mostly did blood draws. They were replaced halfway through the third day by permanent FEMA staff from Iowa and Ohio. We were assigned two phlebotomists and one med tech."

One of the first agencies to show up after the hurricane was the **Agency for Health Care Administration** (AHCA), Florida's laboratory licensing and regulatory agency. "AHCA was here to inspect the entire hospital (including the laboratory) and insure that clinical services were up to standards," observed West. "Our lab was, as we had maintained our procedures throughout the emergency. But AHCA's visit was a lesson that good laboratory practices cannot be ignored.

## FEMA's Lab Personnel

"When FEMA-supplied lab personnel arrived, they were given a full, but rapid, orientation to our laboratory. We also documented everything. Even with all the stresses of this emergency, the laboratory staff continued to follow appropriate procedures," she said.

Another lesson from the emergency was to look at the downstream impact of the disaster and how it affects the flow of patients into the hospital. "The first surge of patients during the hurricane were chest pain patients," explained West. "Then patients injured by the wreckage came in. Days later, some cases of diarrhea, apparently caused by living in the storm shelters, showed up. In the two weeks since the storm itself, we've seen lots of dehydrated individuals—both disaster workers and people cleaning up their property. There is also a steady flow of people injured during clean up, whether from chain saws, clearing debris, or other accidents."

Lab Directors in other Florida hospitals described a similar range of patient cases when contacted by THE DARK REPORT. In fact, the downstream impact of Hurricane Charley was the next lesson mentioned by West.

***Hurricane Charley also had an impact on the ability of hospital laboratories to reach laboratory staff at home and call in substitutes and additional help.***

"In Arcadia, a large number of patients see doctors in Port Charlotte," stated West. "But the doctors' offices in that town are destroyed and closed. So they came to our emergency room (ER). That forced DMH to set up a second ER. But then our laboratory has the challenge of how to report the test results to their primary physician. We are working our way through this problem."

## Delivering Test Reports

This situation was confirmed by staff at **Fawcett Memorial Hospital** (FMH), in Port Charlotte. "With roof damage to our hospital, we were forced to evacuate patients after the storm. Just as our hospital was damaged, a large number of physicians' offices across Port Charlotte are unusable," stated an employee of FMH, who declined to be identified. "Our hospital is setting up portable buildings in the parking lot so that physicians have a place to see their private practice patients."

With a leaking roof at the hospital during Hurricane Charley, med techs were forced to create an "umbrella arrangement" to shield lab instruments from water damage and allow them to continue operating. The laboratory had already moved some equipment in anticipation of possible flooding from the hurricane.

Another lesson gained from the experience of this hurricane is the need for certain areas of the laboratory to be air conditioned after the switch-over to power generators. At Fawcett Memorial Hospital's laboratory, the switch-over to generator power went smoothly. The problem was the lack of air conditioning in the laboratory. Summer heat levels made it difficult to properly operate the chemistry instruments. The lab responded to that situation by sending certain specimens across the street to another hospital laboratory for a day or two.

## Back-Up Air Conditioning

This "crisis lesson" mirrors a similar one learned during the electrical blackout of August 14, 2003 that affected the entire Northeast United States. At that time, several laboratories interviewed by THE DARK REPORT explained that, although generator power had switched on as planned, where labs were not on generator-powered air conditioning, it was difficult to maintain the conditions needed to properly perform laboratory testing.

Lack of generator-powered air conditioning in computer rooms was another lesson, as was, in one case, the inability to produce de-ionized water for certain laboratory tests. *(See TDR, August 18, 2003.)*

Hurricane Charley also had an impact on the ability of hospital laboratories to reach laboratory staff at home and call in substitutes and additional help. This was caused by the widespread lack of electricity in the community and the failure of both regular telephones and cellular telephone systems.

One of the Punta Gorda hospital labs said that it was forced to physically send couriers to laboratory employees' homes. That was the only way to notify them of scheduling changes or if they were needed to fill in for absent employees.

***Continued on page 17...***

# ChromaVision Targets National AP Market

## *Automated cellular imaging technology will support company's expansion*

***CEO SUMMARY: Three new business strategies are moving ChromaVision into different segments of the laboratory testing marketplace. The company has built a new laboratory facility and will support local pathology groups with advanced diagnostic technology. It is also expanding its presence in the research and development area of pharmacodiagnostics, with an emphasis on oncology.***

PROFIT AND OPPORTUNITY are the motivations behind a new business strategy and a new executive team at **ChromaVision Medical Systems, Inc.**, based in San Juan Capistrano, California.

Profit, or rather the lack of it, caused ChromaVision to rethink its existing business model. It was 2000 when it received FDA clearance to sell its Automated Cellular Imaging System (ACIS®). During the past four years, the number of ACIS instruments placed in clinical use has increased steadily. But profits at ChromaVision have proved elusive.

### Two New Executives

Faced with the need to boost profitability, the company is transforming itself. It adopted a three-pronged business strategy. To implement this strategy, it recruited a new senior executive team. On July 22, it announced that Ronald A. Andrew, Jr. was to be the new President and CEO. Then, on August 18, ChromaVision announced that Kenneth J. Bloom, M.D. had joined the firm as Medical Director, effective that day.

Andrews was most recently the Senior Vice President, Global Marketing and Commercial Business Development, for **Roche Molecular Diagnostics**. Bloom was Senior Medical Director at **US LABS, Inc.**, based in Irvine, California.

ChromaVision's two new executives will tackle the company's new, three-pronged business strategy. First, it will expand sales of its Automated Cellular Imaging System into markets outside the United States. Second, it has built a new laboratory facility and will compete directly for specimens with other anatomic pathology (AP) specialty laboratories. Third, ChromaVision is beefing up its involvement with pharmacodiagnostics, including participation in clinical trials to develop proprietary companion diagnostics.

ChromaVision has ample cash to execute these new business strategies. In February 2004, the company received $5 million in new funding from **Safeguard Scientifics, Inc.** ChromaVision is a majority-owned subsidiary of Safeguard. One month later,

in March, ChromaVision closed a $21 million securities offering. It also announced a research collaboration with **UCLA**.

ChromaVision's transformation from a manufacturer and distributor of AP imaging systems based on proprietary technology into a provider of direct testing is an unexpected turn for the company. It now becomes a direct competitor in the lab services marketplace.

ChromaVision's new business strategy is directly rooted in the firm's experience since it introduced ACIS earlier in this decade. It has an automated microscope with computer-based color imaging technology. ACIS can detect, count, and classify cells of clinical interest based on recognition of cellular objects of particular color, size and shape.

## Diagnostics Marketplace

In 2000, ChromaVision obtained a broad clearance from the FDA and focused on market penetration and commercialization of ACIS. This broad FDA 510K allows customers to use ACIS in a variety of ways. In addition ACIS has three specific FDA clearances: MRD Micrometastases (2000), Estrogen Re-ceptor and Progesterone Receptor (2002), and HER2 (2003).

ChromaVision estimates that about 30% of all new cases in these areas run on its ACIS at hospitals and research labs across the country. It says it has about 261 customers in the clinical market and 35 customers in the research market.

To pursue its new business strategies, ChromaVision ended its long-standing relationship with **US Labs, Inc.** in June 2004. The partnership processed specimens and provided imaging to customers via CD/DVD/Web. The referring pathologists determined the cells to be evaluated, performed the diagnosis, and billed for the professional component.

ChromaVision intends to perform these services itself. It built a new laboratory in San Juan Capistrano. As a reference laboratory service provider, ChromaVision starts from a strong position. It has an installed base of 166 ACIS placements and 95 ACCESS workstations. It is also modeling its operations on the successful things done by other national AP labs. A number of its recently-hired laboratory staff have come from these companies, including **IMPATH**.

As its three new business strategies gain traction in the marketplace, ChromaVision Medical Systems has the potential to become a new type of laboratory/diagnostic business model. It is using ACIS, a proprietary imaging technology, to develop a unique relationship with its anatomic pathologist-clients.

ChromaVision can sell its full ACIS system to pathology laboratories seeking to do 100% of the work themselves. Alternatively, ChromaVision can have a role as an esoteric reference laboratory, providing technical services, then transmitting the resulting AP images to the referring pathologist. Alternatively, it can perform both the technical and the professional services at a client's request.

## Diagnostics Marketplace

ChromaVision Medical Systems demonstrates that the national marketplace for anatomic pathology services continues to evolve. New business forms and new professional relationships between diagnostic technology developers and laboratories are steadily reshaping all aspects of the laboratory testing marketplace.

It is another example—and another early warning—to local anatomic pathology group practices that their profession is evolving. **TDR**

*–By June Smart, Ph.D.*

# Oncology's Potential Drives AP Lab Expansion

## *ChromaVision is the latest company wanting to expand its presence in cancer diagnostics*

***CEO SUMMARY:*** ***It is no coincidence that another public company is shifting its business focus and expanding its efforts to capture cancer-related anatomic pathology specimens. Demographic trends predict a steady increase in the number of new cancer cases yearly, while new technologies are giving physicians more effective ways to detect cancer and treat it. That is why cancer diagnostics is viewed as a "hot market."***

LIKE MANY NEW TECHNOLOGIES which enter the diagnostic marketplace, the Automated Cellular Imaging System (ACIS®) developed by **ChromaVision Medical Systems, Inc.** has had its critics within the pathology profession.

Using computer images and a proprietary software system, ACIS is one of the first products to offer anatomic pathologists a way to produce quantitative, standardized immunohistochemistry results. It was no surprise to market observers that some within the pathology profession expressed opinions and doubts that this type of technology could do a better job than that currently delivered by competent and experienced pathologists.

Independent of that debate, however, are the actions taken by individual pathology groups to acquire this technology and put it into clinical use. During the past four years, ChromaVision reports that 261 clinical customers acquired the ACIS technology. To put this market penetration into perspective, there are approximately 3,300 pathology group practices in the United States. ACIS placements in clinical settings would indicate that possibly 7% of pathology groups in the United States now use this tool in their clinical practice.

Following the FDA's clearance of the ACIS for clinical use, it took only 48 months to achieve this market share. Independent of ChromaVision's profitability as a company, this steady gain in market penetration is a message that the pathology profession's early adopters are responding to technology and tools which enhance the clinical services they provide to referring physicians.

### New Lab Testing Provider

Against this background, THE DARK REPORT considers it significant that ChromaVision now wants to expand its business and became a direct provider of laboratory testing services. For the anatomic pathology profession, this sends several messages--all of which should get strategic attention.

One, ChromaVision is uniquely positioned to evaluate both the current size and future growth in the market demand for immunohistochemistry tests. Investments in its new laboratory and its plans to directly provide such tests are signs that ChromaVision expects robust growth and adequate reimbursement in this area of diagnostic testing.

***Certainly this product, along with the change in personal practice patterns it represents, has critics within the pathology profession.***

Two, ChromaVision's three strategic business initatives each expand the company's presence in the oncology marketplace. This reinforces and further validates a prediction made by THE DARK REPORT during the past 24 months: oncology will be one of the most dynamic, fast-growing, and profitable sectors of laboratory testing.

ChromaVision's investment to position itself in oncology diagnostics follows those made since 2002 by **Laboratory Corporation of America** (which paid almost $600 million to acquire **DIANON Systems, Inc.**), **Welsh, Carson, Anderson, and Stowe** (which acquired **AmeriPath, Inc.** for $849 million), and **Genzyme Corp.** ($250 million invested to purchase **IMPATH, Inc.** and **AlphaGen**). Each investment is a major bet to guarantee a significant role in oncology diagnostics.

## Shift From Local Pathology

Three, ChromaVision's desire to enter the national marketplace as a direct provider of (AP) testing services is another sign that anatomic pathology is steadily shifting from a local business, dominated by local AP groups, to a national business. AP groups which fail to respond to this powerful trend will lose access to patients referred by office-based physicians in their community.

Four, the pathology profession should recognize that ACIS is representative of a new class of technology. It is technology which is designed to increase the diagnostic accuracy of pathologists, improve the uniformity of diagnoses between individual pathologists, and enhance the clinical added value that a pathologist provides to referring physicians.

Five, as the use of ACIS and similar technology continues to expand within the anatomic pathology marketplace, it will drive two other outcomes. First, these types of tools will tend to increase specialization within anatomic pathology. The generalist pathologist without any subspecialty expertise will find those skills in declining demand. Second, it will raise the expectations of referring physicians, who will want to see a higher quality of test result reporting.

## Critics Versus Advocates

Certainly this product, along with the change in personal practice patterns it represents, has critics within the pathology profession. But it also has its advocates. The number of ACIS units placed in clinical settings demonstrates that fact.

As pathologists become more centralized players in the diagnostic picture and patient care they will start to look to technological assistance to make them more efficient, accurate, and precise in their diagnoses.

Patient safety, error reduction and quality medicine is becoming a public mantra. Pathologists will need technologies like that offered by ChromaVision if they are to continually increase the quality of services they provide to payers and the public alike. TDR

***CEO SUMMARY: Are Lean and Six Sigma techniques ready to make a big contribution in the laboratories of smaller hospitals? If you ask lab managers at Mayo Clinic's Scottsdale Hospital, the answer is an unqualified "Yes!" Their 15-week Lean project in the hospital's high volume core laboratory produced worthwhile improvements. It also formed the foundation for expanding Lean methods into other parts of the lab, as well as other departments within the hospital.***

## MAJOR GAINS FOR 193-BED HOSPITAL LAB

# Mayo's Scottsdale Hosp. Lab Hits Big "Lean" Home Runs

QUALITY MANAGEMENT METHODS of Lean and Six Sigma are transforming laboratory operations at **Mayo Clinic's** hospital in Scottsdale, Arizona.

This is a noteworthy development. First, when Mayo Clinic speaks about healthcare innovation, people listen. It is one of the nation's most credible medical institutions.

Second, Mayo Clinic's hospital is a 193-bed facility, not big by industry standards. Yet it was willing to underwrite the cost of a major Lean/Six Sigma makeover of its high volume core laboratory because of the resulting downstream benefits.

This Lean-based makeover is an important demonstration of how quality management methods can boost the performance of laboratories located in smaller hospitals. It demonstrates they have the same opportunities, albeit with a smaller specimen volume, to slash test turnaround times, boost quality, and increase productivity.

THE DARK REPORT recently visited the Mayo Clinic Scottsdale Hospital to learn, first-hand, how and why Lean/Six Sigma techniques made such a big difference. Enthusiasm for the changes was obvious. The laboratory staff was proud of the project and its outcomes.

"Since the construction of this hospital in 1998, we've had explosive growth in patient volume," stated Linda Pearson, Laboratory Operations Administrator at Mayo Clinic Hospital in Scottsdale. "Not only is our hospital a major transplant center, but it services a significant number of outpatients.

"Like laboratories in other fast-growing hospitals, we found ourselves squeezed for space and stretched to the maximum for lab test capacity," she said. "Even though our laboratory was relatively new and was designed around 'best practices', the steady growth in specimen volume was pushing our operational capabilities to the limit.

"I recognized the potential of quality management methods, like Lean and Six Sigma, to fundamentally change the operational philosophy of our laboratory and push it to a significantly higher level of performance. I also believed it would enhance the day-to-day working environment for our medical technologists and staff, allowing them to contribute more with less stress," she explained.

Pearson's first step was to bring in a consultant to assess the existing situation, identify opportunities for improvement, and provide projections on the resulting cost savings. "I knew that, before I could get the money to fund this Lean project, I had to make both a clinical case and a business case to my hospital administration," Pearson said.

### Making The Business Case

"We did our homework. The consulting group we used was from **Ortho-Clinical Diagnostics** (OCD), a **Johnson & Johnson** company," she said. "Our presentation to hospital administration covered all the bases. We were given a budget and a top-level commitment to succeed. We were also told that we would be watched closely. If this Lean project achieved our objectives in the lab, administration would be ready to introduce Lean techniques in other departments in our hospital."

The assessment and budget authorization took place in the fall of 2003. Pearson's next step was to pick a lab team to implement the Lean project. "In our hospital lab and clinic lab, there are 153 FTEs," she said. "We had 17 people volunteer for the eight Lean team positions! That's because many in the laboratory were excited about the opportunity to fix problems and make this a better working environment. The Lean project was scheduled to take 15 weeks and would require a full-time effort from the eight team members.

"We conducted interviews and selected our team in time for a February start," added Pearson. "OCD had already done the assessment, so our plan of attack was

## Laboratory Outcomes From Lean Project

**IN PREPARING FOR ITS LEAN PROJECT**, the laboratory at Mayo Clinic Hospital in Scottsdale, Arizona identified high volume, automated testing as the likely source for major improvement.

Total test volume at this laboratory site is 700,000 billable tests per year. The Lean project targeted automated chemistry, hematology, and coagulation. These three areas of the laboratory generate 90.8% of total test volume.

Upon completion of the Lean project, which lasted from February through May, 2004, the following outcomes were generated:

- Reduction in average turnaround time of 37% (order to verfied result).
- The new work cell configuration requires two less FTEs to run the same number of instruments. Those individuals now perform other duties in the lab.
- Overall productivity improvement of 27% as a result of the first Lean project.

ready. The first week was spent teaching our Lean team about the fundamentals and principles of quality management. Then the hard work began.

"The Lean project targeted our high volume core laboratory. Automated chemistry, hematology, and coagulation represents 90.8% of our total test volume. Every improvement in this section of the laboratory would produce significant gains," explained Pearson.

Those operational gains are listed in the sidebar above. The outcomes are of the same magnitude and scale as the outcomes of other hospital labs' Lean/Six Sigma projects that the THE DARK REPORT published last year. *(See TDR, September 8, 2003.)*

Because it is a laboratory in a smaller hospital, several aspects of this Lean project are particularly interesting. One potential issue was whether the laboratory staff would accept and support a major transformation of their daily work routines. Lab staff reaction and involvement will be the theme for the remainder of this intelligence briefing.

"At the start, our biggest hurdle was to convince people that their daily work patterns were not the best possible. There was a better way to do that work," stated Mike Mansfield, Lead Technologist on the day shift and a member of the Lean Team.

"Our approach was to help them understand two principles to our Lean makeover," he explained. "One, there would be no change to the fundamental protocols used to perform our tests. We were not tinkering with the science behind the test result. Two, our change efforts would be focused on the operational processes which supported the analysis of the specimen.

"One message was stressed throughout: 'To help you do a better job, we are eliminating the obstacles and barriers'," said Mansfield. "That could mean reducing the number of steps they had to walk as part of their routine or simply eliminating phone calls that disrupted their work."

### Fix Poor Work Processes

"In particular, the med techs needed to know that no one was challenging either their technical skills or their performance. The single objective of this Lean project was to attack the organizational impediments and hurdles that created the same problems every day," added Linda Paige, Systems and Procedures Manager for Mayo Clinic Scottsdale and a member of the Lean team.

"Once the laboratory staff understood this was not about them, but was about improving our work flow and work processes, we began to see increased support and enthusiasm,"

declared Pattie Glick, Laboratory Manager. "Because quality management methods are data-driven, our med techs quickly grasped how the numbers helped us identify bad processes and operational bottlenecks. For them, this was credible evidence that a specific work process should be changed."

## Non-Negotiable Objectives

"From the outset, we did make clear that there were non-negotiable items and negotiable items," explained Pearson. "These ground rules could not be broken. For example, two non-negotiable items were single-piece flow (not batch) and standard work methods. Two negotiable items were process sequence and operator walk patterns."

"These are easy to illustrate," interjected Mansfield. "For example, all phlebotomy was converted to 'draw one person and send the specimen to the laboratory' before doing another draw. That is single-piece flow versus batch. It was non-negotiable. However, in establishing a single layout and supply inventory for all phlebotomy carts, the phlebotomists could make suggestions and negotiate the final configuration of the cart."

"There was another concern we had to address as we started the Lean project," noted Tom Leto, Lean team leader. "Many individuals were apprehensive prior to the start of the project. They asked questions like 'how will I fit in after the Lean project? Will I lose my job? Will my job change?'

"Questions like these quickly taught us the importance of clear, detailed, candid, and frequent communications," said Donna Passante, Quality Coordinator and a Lean team member. "We had hospital administration speak to the laboratory staff about their support of the Lean project. We held regular meetings and provided frequent written updates.

"You must over-emphasize communication," continued Passante. "Med techs often have a decade invested in one job done in one way. These are deeply-ingrained patterns that a Lean project disrupts. We were compassionate, but unyielding, about processes that needed to change. That is where using data helps the staff understand why specific changes must be implemented."

During THE DARK REPORT'S site visit, Lean team members offered some practical pearls of wisdom. These were gleaned from their experience at introducing Lean and Six Sigma quality management principles into their laboratory.

"Using Lean made us recognize how often, pre-Lean, our management approach was to use a 'work-around' to solve a problem," said Becky Stewart, Microbiology Supervisor. "Inevitably, once you gather accurate data, you see that a 'work-around' fix only added complexity—even errors—to the overall work flow. "

## Utilize Experts

"An important reason for the success of this Lean project is that we didn't try to 'home grow' it," observed Glick. "It was important to bring in experts who could teach us these techniques, show us how to apply them in real-life situations, and offer us practical wisdom that comes from having done this in other laboratories multiple times. Most importantly, they could insure that we implemented Lean and Six Sigma techniques correctly and hit our goals.

"Another key insight from our experience is that our work processes now treat all specimens equally, " continued Glick. "We don't separate specimens by classes of patients—stroke versus transplant, for example. Our work processes now allow us to treat all specimens the same, as well as to

meet and exceed our targets for turnaround time, quality, and reduction of errors. That's been a major benefit from our Lean experience."

"It is important to also mention that Lean is not a universal problem solver," offered Mansfield. "Lean is a mindset, a philosophy, and a set of tools to solve part of the management issues involved in laboratory operations. But many lab management issues remain which require attention. In fact, some of these issues originate outside the laboratory."

## Growing Use of Lean

Lean management methods appear to have established themselves within the Mayo Clinic Scottsdale Hospital. Lean projects are being planned, not only for the laboratory, but for other departments within the hospital. There are also plans to introduce Lean methods into the laboratory at the Mayo Clinic Scottsdale, which is at a separate location away from the hospital.

"What continually amazes all of us in laboratory management is how differently we now view lab operations and work processes," offered Pearson. "By simplifying our work flow and individual work processes, by eliminating waste, and by reducing cycle time, it has dramatically changed our laboratory's working environment.

## Learning To Love Lean

"A growing number of our laboratory staff understand this new management philosophy," she said. "Once the changes are in place and they become familiar with the new routines, they appreciate how the design of the system greatly affects their ability to improve quality, generate test results faster, and deal with fewer system-generated errors."

Pearson also had another comment, one that profoundly touches the future of laboratory management. "Automation and new diagnostic technology, properly operated, means that most labs will soon generate results of comparable quality," she observed. "When that day arrives and all labs get the same clinical answer, then the point of differentiation will shift in favor of laboratories organized around better work flows and better work processes! Lean is helping our laboratory develop that differentiation."

Pearson's prediction should give pause to all laboratory directors and pathologists. If the day arrives when almost every laboratory delivers the same, high-quality test result, competitive advantage will accrue to labs which differentiate themselves in other ways.

In fact, that is just what Linda Pearson is doing with her laboratory. As a leader, she visualized how Lean and Six Sigma management methods could provide that to her laboratory organization. As a champion of this idea, she sold it to senior administration and obtained both scarce capital to fund the project, as well as the support of Mayo Clinic Scottsdale's top leadership.

This a good example of how laboratory leaders can change the status quo in radical ways. It is also a great example of how leadership can stimulate positive change even in smaller hospitals. The laboratory at Mayo Clinical Scottsdale Hospital is farther down the Lean/Six Sigma road than the **Mayo Clinic Rochester** laboratory or **Mayo Medical Laboratories**.

Laboratory administrators and pathologists willing to push forward with innovation should take inspiration from the experience of the laboratory at Mayo Clinic Scottsdale Hospital. Good ideas, implemented for the right reason, are difficult to stop. The laboratory director and her management team at this 193-bed hospital have just demonstrated that fact. TDR

*Contact Linda Pearson at 480-301-7411.*

# Hospital Laboratory at Mayo Clinic Scottsdale Uses Lean Methods to Improve Performance

**At the laboratory of Mayo Clinic Scottsdale Hospital**, the Lean project achieved significant improvements in several areas. Here are some key findings of this Lean project.

## Types of Waste in the Lab

- Waiting
- Tray of specimens waiting for tech to process
- One specimen in a batch waiting to be processed
- Overprocessing
- Excessive incubation or mixing
- Excess motion
- Techs leaving the workstation to get more reagents or specimens
- Inventory
- "Stashes" of supplies
- Samples batched up for analysis
- Results awaiting confirmation and release
- Defects
- Failure to get the proper result for the proper patient to the proper physician
- Retest that could have been avoided

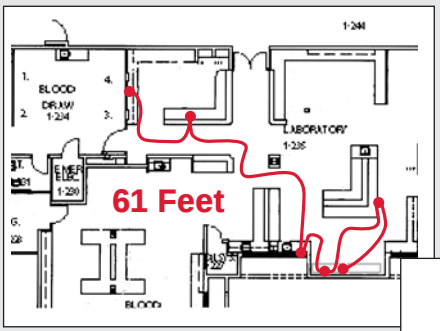
## Non-Negotiable Items

- Standard Work Methods
- One Piece Flow
- Balanced Distribution of Work
- Standard Work in Process
- Visual Management Control
- TAT Time – Pace
- Moving/Standing Operations
- FIFO Materials

## Negotiable Items

- Process Sequence
- Part/Tool Sequencing
- Tool Size/Type
- Visual Control Design
- Stock Inventory (Quantity)
- Operator Walk Patterns

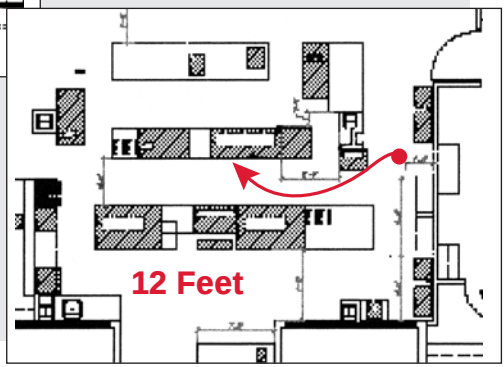
**Shown below is how the redesign** of automated chemistry, hematology, and coagulation into a single work cell reduced the walk distance by 89%, while slashing turnaround time, improving quality, and boosting productivity.




## ◀ Old Hematology Flow

**"Before" Walk Distance**

Heme .....328 ft
Coag .....371 ft
Chem .....857 ft
Total.....1,556 ft




## New Hematology Flow ▶

**"After" Walk Distance**

Redesigned Cell .....171 ft
Total .....171 ft

***89% Improvement***

## The Dark Index

# Leonard Joins AEL's Board, Cenetron Is Newest Acquisition

*Start-up reference and esoteric lab company almost ready to open its Dallas lab facility*

There were two big announcements at **American Esoteric Laboratories, Inc.** (AEL) during the past few weeks.

First came news on July 20 that Larry L. Leonard was now on the Board of Directors at AEL. Leonard had been part of the senior executive team at **Laboratory Corporation of America** from its formation in 1994 until his resignation in 1998. Prior to 1994, Leonard worked at **National Health Laboratories** for 16 years. Leonard has provided strategic consulting services to AEL during its formation and start-up.

That news was followed by the disclosure, on August 20, that American Esoteric Laboratories had acquired "the commercial molecular testing assets" of **Cenetron Diagnostics, Ltd.**, based in Austin, Texas. Cenetron was formed during the 1990s. Its President and CEO, Dwight B. DuBois, M.D., holds a number of patents for molecular-based technologies.

### Molecular-Based Assays

Cenetron offers molecular-based assays in a number of areas, including infectious disease, cystic fibrosis, and Factor V Leiden mutation analysis. In the late 1990s, Cenetron collaborated with **Ambion, Inc.** to develop "armored" segments of RNA for use in HIV and HCV testing.

Besides offering clinical molecular testing in Texas, Florida, and other southeastern states, Cenetron also maintains a presence in clinical trials. Its research and development division develops custom assays for selected customers.

Cenetron is AEL's third acquisition. The company, headquartered in Brentwood, Tennessee, purchased two laboratories in early spring. Both were located in Dallas, Texas, where AEL is currently building its central reference laboratory. That laboratory is expected to be fully operational within eight weeks.

American Esoteric Laboratories is the newest lab company to target the national market for high-end reference and esoteric testing. It received $70 million in venture capital funding. *(See TDR, April 26, 2004.)*

AEL is currently hiring and training its sales and marketing staff. Once the new laboratory facility in Dallas becomes operational, AEL's sales team will hit the marketplace to develop new clients. AEL wants to specifically target the esoteric send-out business of hospitals and specialist physicians.

The potential for this company to succeed should not be underestimated. The last "start-up" of a national reference/esoteric lab company was **American Medical Laboratories** in 1997. When it was sold in 2002, the purchase price was $500 million! TDR

# Lab Industry Briefs

## CERNER CORP. ACQUIRES GAJEMA SOFTWARE

WITH ITS ACQUISITION of **Gajema Software**, announced on August 17, **Cerner Corporation** is moving an existing four-year business relationship to a higher level.

Gajema, based in Charlotte, North Carolina, sells a solution to help labs track specimens from the pre-analytical operations of their outreach programs through analytical and post-analytical functions.

"During the four years of this partnership, a complementary fit between our two organizations developed," stated Greg White, formerly CEO of Gajema and now a Vice President with Cerner. "As our sales to individual laboratories increased in recent years, it became clear that Gajema and our clients would benefit from the synergy between the two company's products and services.

"Gajema unifies completely with Cerner Laboratory Outreach solutions, enabling labs to track specimens from the point-of-collection through results reporting," he said. "We will maintain a full product suite for non-Cerner customers," he observed. "In parallel, Gajema products will be integrated as appropriate with Cerner's products. In fact, it is that type of collaboration which brought our companies together originally."

Gajema's original product was focused exclusively on logistics. Laboratories used it for point-to-point specimen tracking, dispatch, and other logistics functions. That gave Gajema the platform to develop additional functions now used in client services, supply distribution and utilization measurement, quality control, metrics management in the outreach program, and other functions. According to White, 100% of the Gajema staff remained after the merger. Continuity of service and product development is continuing without interruption.

## OUTSOURCING LAB TESTS TO INDIA: BIG DUST-UP IN THE UNITED KINGDOM

There's been widespread publicity in this country about the outsourcing of jobs to India. So far, healthcare services are not involved in this activity.

One of India's most aggressive laboratory companies is actively looking for outsourcing opportunities in the United Kingdom. Last month, a British newspaper printed a short news item that **Ranbaxy Laboratories Ltd.** of New Dehli, India had met with officials from the **National Health Service (NHS)** explore ways to provide India-based lab testing services in the U.K.

This triggered a flood of critical comments by pathologists and laboratory administrators in the United Kingdom. The NHS issued an official statement disavowing any plans to send lab specimens from the U.K. to labs in India. THE DARK REPORT believes that it was actually a clever bit of marketing one-upmanship by Ranbaxy, which, at its own initiative, solicited a meeting with NHS officials.

That said, the United States is also on the radar screen. In the last six weeks, THE DARK REPORT has been contacted by two different entities representing laboratory companies in India. They are actively evaluating the viability of outsourcing U.S. lab specimens to India. More to come on this unfolding story. TDR

*Continued from page 4...*

The widespread power outage in residential areas also had another effect on laboratory operations. Lab staff living in areas without power had no way to do laundry and other necessary chores of daily living.

At Fawcett Memorial Hospital's laboratory, staff living in Sarasota, which still had full power, were doing laundry for lab employees living in areas without power. They would also bring in water, and help with clean-up efforts at other lab employee's damaged homes. FMH also established a day care center within the hospital as a way to help employees during the emergency.

FMH staff picked up another category of illness attributable to the effects of Hurricane Charley: respiratory cases caused by mold in homes. Without power and air conditioning, worsening mold conditions in residences were contributing to a growing number of ER visits by affected individuals. There was also a case of six family members suffering carbon monoxide poisoning from the generator operating within their home.

***Some of these lessons are reminders. For instance, contingency plans should allow lab instruments and LIS to operate with both power and air conditioning as necessary.***

Hospital laboratories on the periphery of Hurricane Charley had a relatively easier time. For example, **DSI Laboratories** was farther south on the coast. Located in Fort Meyers, Florida, it survived high winds with minimum damage to its laboratory facility.

"DSI's main laboratory did lose power and its telephone connections," stated Martha Sunyog, Director of Laboratories at **Naples Community Hospital**, one of the labs in the DSI network. "This happened at 2:00 a.m. the next morning, after Hurricane Charley had passed by. It meant no access to the computer system, so there was lots of hand entry of orders and results.

"Courier services were maintained and our contingency plans help up well," she added. "DSI's patient service center in Port Charlotte was damaged. It was relocated and phlebotomy services in that area were maintained."

THE DARK REPORT notes that this was a difficult story to research. Even two weeks after Hurricane Charley blew through Florida, hospital laboratories in the communities most affected by this storm have yet to return to any semblance of normal. Laboratory directors are still responding to extraordinary demands and needs.

## Appreciation And Thanks

So it is with much appreciation that THE DARK REPORT would like to thank all who took time to stop and contribute to this story. Their willingness to share the management lessons learned is much appreciated by all our clients and regular readers.

Some of these lessons are reminders. For instance, contingency plans should allow lab instruments and LIS to operate with both power and air conditioning as necessary. But others are insights often overlooked.

Does your laboratory have a contingency plan to contact lab staff at home, after an emergency, if they don't have electricity or telephones? Is your laboratory ready to deal with an evolving range of patient visits to the ER which mirror the longer-term consequences of a natural disaster? These are valuable issues to consider now, while there is time to craft a solution into your lab's contingency plan. TDR

# INTELLIGENCE

## LATE & LATENT

*Items too late to print, too early to report*

Film-maker Michael Moore is ready to turn his cameras on the American healthcare system. During a tour of the United Kingdom this summer, the controversial director declared that he wanted to use his cameras to intervene and save lives. Moore, basking in the attention generated by his *Fahrenheit 9/11* film, wants to "embarrass" health insurance companies and hospitals into providing care for uninsured individuals. Given Moore's reputation for playing loose with facts, any documentary he produces on healthcare in the United States will certainly be controversial.

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### TEN-MINUTE CD4 COUNT

In Austin, Texas, a new biotech company is developing lab-on-a-chip technology to perform, from a single drop of blood, a ten-minute CD4 count on HIV/AIDS patients. **LabNow, Inc.** uses an automated reader the size of a toaster to process assay-specific biochips. The nanotechnology which enables this process was invented at the **University of Texas**.

### HOSP. DOC'S NECKTIES AGAIN CONFIRMED TO HARBOR BACTERIA

Once again, a study demonstrates how clothing worn by physicians in a hospital can become contaminated with pathogens. Earlier this year, physicians at **New York Hospital Medical Center of Queens** tested for bacteria on 42 ties worn by physicians, physician assistants, and medical students working at the hospital. Of the tested ties, one in four held *Staphylococcus aureus*. One in eight ties contained hospital-acquired bacteria, including *Klebsiella pneumonia*, *Pseudomonas aeruginosa*, and *Acinetobacter baumannii*. Researchers also tested 10 ties worn by security guards at the hospital. Only one of these ten ties tested positive for a pathogen.

### ADD TO: *Doctors' Ties*

At **Montefiore Medical Center** in Bronx, New York, Lawrence Brandt, M.D. said "My prediction is there will be a number of physicians who will stop wearing ties based upon this." Brandt is Chief of Gastroenterology at the hospital and has studied how physicians' attire affects their credibility with patients. In past years, studies have shown that stethoscopes, pens, and white coats can often harbor germs. "We did not find that the neckties carried what we considered to be the most serious bacteria," observed James J. Rahal, M.D., a researcher involved in the study. "We were looking for the super bugs. We did not find them." This study was reported at the spring meeting of the **American Microbiology Association**. By the way—bow ties are not exempted! A 1993 study of gynecologists and obstetricians found similarly high levels of bacterial contamination on both straight ties and bow ties.

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Publication of THE DARK REPORT'S special two-part series on the trend of specialist physicians capturing anatomic pathology revenues caused quite a stir in both the urology and gastroenterology communities—and that's not all! Copies reached certain elected officials in Congress and were studied with great interest. Expect more breaking news on this major topic.

***That's all the insider intelligence for this report. Look for the next briefing on Monday, September 20, 2004.***

THE DARK REPORT

# UPCOMING…

- ***America's "Best Quality" Clinical Lab: Why This Award-Winning Arizona Lab Can Make That Claim.***
- ***Sifting Deeper into the UroCor Criminal Indictments: Could Other Labs Have Similar Exposure?***
- ***New Lab Instrument Systems: Market Changes Causing IVD Manufacturers To Shift Emphasis and "Hit the Road."***

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