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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 3

COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Battles Continue Over Doctor Mark Up of Lab Tests

FROM THE SHADOWS OF A PARKING GARAGE, Deep Throat suggests to reporter Bob Woodward, "Follow the money." In this scene from the movie, *All the President's Men,* Woodward gets the right advice he needs from an unnamed source to pursue the Watergate case, a huge political scandal of the 1970s.

"Follow the money" is also good advice for lab managers and pathologists tracking the battles over physician mark-ups of clinical laboratory testing and anatomic pathology (AP) services. Efforts of the federal **Centers for Medicaid & Medicare Services** (CMS) to implement proposed rules preventing physicians from marking up certain laboratory, pathology, and radiology services have been widely publicized. Now legislators in Missouri are considering changing state law to prohibit physicians from marking up fees for pathology services. "In some medical practices across Missouri, doctors are turning a profit from lab work done by other doctors. And most patients and their insurance companies don't know about it," says an article in the Springfield *News Leader* in Missouri on April 30. "It's called 'indirect billing' or 'pass-through arrangements,' and a bill in the Missouri legislature would outlaw the practice."

The sponsor of Senate Bill 817 is Missouri state Senator Jack Goodman (R-Mount Vernon). He believes it's unethical for physicians to mark up fees for work performed by other physicians. A similar measure, House bill 1990, is expected to be assigned to a committee. Two earlier efforts to pass such bills failed. Missouri physicians have testified in favor of retaining the ability to mark up test fees, saying it allows them to negotiate discounts with labs and guarantees their patients a set package price for in-office tests and lab work. They claim this can allow them to pass on discounts to low-income and insured patients. But no one has stepped forward with evidence documenting that physicians do, in fact, pass these discounts along to self-paying patients.

I suspect federal officials will prevail in their efforts to prohibit physicians from marking up laboratory tests, anatomic pathology services, and radiology procedures not performed in their offices by board-certified physicians who are partners/employees of the medical group. As that happens, private payers will fall into line with similar anti-markup requirements. After all, if you follow the money, Medicare, Medicaid, and private health insurers have much more to lose than office-based physicians have to gain from banning mark-up arrangements. TDR

Lab Automation Advocates Gather in Kobe, Japan

Sixth Biannual "Cherry Blossom Symposium" provides look at the cutting edge of lab automation

CEO SUMMARY: Everything relating to automation in clinical laboratory operations was the theme of the sixth "International Conference of Laboratory Automation and Robotics," conducted last month in Kobe, Japan. Because laboratories in Japan, Korea, and Taiwan have two and three decades of experience with extensive automation, presentations at this gathering are quite sophisticated and reveal that these laboratories are continuing to push forward in their use of automation.

ALMOST 300 LABORATORY DIRECTORS, PATHOLOGISTS, AND VENDORS gathered in Kobe, Japan, last month for the sixth "International Conference of Clinical Laboratory Automation and Robotics."

Little-known in the United States and Europe, this meeting started in 1998 and takes place in April of every second year. Because this is the time when cherry blossoms are in full bloom across Asia, the conference is also known as the "Cherry Blossom Symposium."

Japan is the world's hotbed for the use of automation and robotics in clinical laboratories. A significant amount of the lab automation products sold throughout the world were developed in Japan and licensed to the world's major *in vitro* diagnostics (IVD) manufacturers.

For that reason, this conference is a great help in understanding why clinical laboratories in the Far East have embraced lab automation for almost three full decades, in ways that frequently confound their counterparts in North America and Europe. That's because hospital laboratories in Japan, Korea, Taiwan, and China commonly use total laboratory automation (TLA), along with fully-automated systems for pre-analytical functions and even automation of phlebotomy and specimen collection.

Conducted as a scientific meeting, each Cherry Blossom Festival is organized by a different group of pathologists and laboratory scientists from a host city. For 2008, the laboratory team at **Kochi Medical School** took the lead in hosting the events. Chairman of this sixth Cherry Blossom Symposium was Tetsuro Sugiura, M.D., who

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SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes THE DARK REPORT plus timely briefings and private teleconferences, is $13.10 per week in the US, $13.70 per week in Canada, $14.85 per week elsewhere (billed semi-annually).

is Professor and Head, Department of Laboratory Medicine at Kochi Medical School. Dr. Sugiura is recognized as one of the pioneers in laboratory automation in Japan. He and his colleagues proved to be great hosts and the symposium was chock-full of useful information and news about innovations in automation.

THE DARK REPORT was there to deliver a presentation, to participate in the sessions, and to conduct site visits of laboratories and IVD companies in Japan. Collectively, these experiences generated several useful insights for lab administrators and pathologists in Western countries. The experiences on this trip certainly advanced THE DARK REPORT'S thinking on laboratory automation and its future in developed countries across the globe, including the United States.

Lab Automation In Asia

One fact stands out about laboratory medicine in Japan, Korea, Taiwan, and China. Compared to the United States and most European countries, hospitals in Asia are typically large—and often have an attached outpatient clinic which treats thousands of patients daily. Thus, laboratories on this side of the world see patient volumes that dwarf the largest hospitals in the United States and Europe.

For example, in Seoul, Korea, the **Asan Medical Center** (AMC) at the **University of Ulsan College of Medicine** is a 2,800 bed facility. Its attached outpatient clinic will be treating 10,000 patients per day by the end of 2008! In 2007, the lab performed 30.9 million tests.

The lab's goal at AMC was "one stop service," meaning that "patients can visit his or her physician with test results as soon as possible in the same day after specimen collection." Projects at AMC's lab to accomplish this were presented by Won-kin Min, M.D., Ph.D., Professor of Laboratory Medicine at the Ulsan College of Medicine. Predictably, with the main lab's analytical processes already automated, attention was given to specimen collection, specimen transport to the laboratory, and specimen processing in the laboratory. Dr. Min reported that projects to add another specimen collection room and another rapid response laboratory were under way to achieve the desired reduction in average lab test TAT.

Data Mining In The LIS

Use of information technology to advance laboratory medicine services is also occurring in Japan and surrounding countries. At the **Yamaguchi University Graduate School of Medicine** in Ube, Japan, Kiyoshi Ichihara, M.D., Ph.D. and his colleagues are using sophisticated software tools to data mine the laboratory test results in the laboratory information system (LIS). Ichihara, who is Professor, Department of Laboratory Sciences at Yamaguchi University, discussed a variety of ways to tease useful clinical knowledge from the lab test data residing in the LIS.

His goal is to develop a life style disease prediction system that, in part, can look at the results of unrelated lab test results and identify patterns consistent with disease, then proactively intervene with the patient to achieve positive health outcomes.

Visits To Sysmex And Labs

During this trip of nine days, THE DARK REPORT was also able to visit **BML, Inc.'s** main laboratory, located in a Tokyo suburb. It serves up to 150,000 patients per day and a report of that site visit was distributed as a *Dark Daily* e-briefing. We also had an executive briefing at the headquarters of **Sysmex Corporation** in Kobe, followed by a site visit to the Sysmex main manufacturing facility in Kakogawa. Another high point was our tour of the **Tokyo University Hospital Laboratory**. *(See pages 5-7.)*

Combined, participation at the Cherry Blossom Lab Automation Symposium and the site visits provided excellent information on why lab automation is so enthusiastically embraced in Japan and other Asian countries. TDR

Univ. of Tokyo Hospital Lab Has Plenty of Automation

Phlebotomy is supported by extensive automation, most interesting is the automated urine transport line

CEO SUMMARY: In Japan, many clinical laboratories are in their third decade of using automation. At the University of Tokyo Hospital, total laboratory automation (TLA) was first implemented in 1991. Now on its fourth generation TLA system, this laboratory was worked upstream to automate specimen collection and urine collection, transport, and specimen preparation. The result is automation solutions not seen in the United States.

JAPAN IS THE UNQUESTIONED WORLD LEADER in clinical laboratory automation. One example of a highly-automated hospital laboratory can be found at **University of Tokyo Hospital**, in Tokyo, Japan.

Last month, while in Japan, THE DARK REPORT was privileged to tour this laboratory. University of Tokyo Hospital (UTH) has 1,210 beds and its laboratory serves a related outpatient clinic that sees approximately 3,300 patients per day.

The tour was arranged by **Sysmex Corporation** and was conducted by Hiromitsu Yokota, Ph.D., Technical Supervisor, Department of Clinical Laboratory at UTH. Because the tour was conducted in Japanese and translated to English, THE DARK REPORT acknowledges, in advance, that any inaccuracies in the information which follows are probably due to translation errors.

The high volume core laboratory at UTH is an open lab design. A phlebotomy and specimen collection area is located at one end of this laboratory space. UTH draws approximately 2,000 patients per day and handles 9,000 individual tubes and specimens daily. The majority of patient blood draws are done at this location. Phlebotomy is also done in several other areas of the hospital and tubes are transported to the lab via a pneumatic tube system.

The extent of automation at the UTH laboratory can be illustrated by describing two ways in which phlebotomy is supported by automated systems. First, automation is used extensively to support phlebotomists in the collection process. Patient test requests are transmitted to one of two automated systems that verify the information, then prepare the specimen collection supplies needed for each individual patient. These automated systems prepare bar code labels, pick the right tubes or other collection supplies, apply the labels and then produce a collection tray specifically for that patient.

For the automated system that supports the primary collection site next to the high volume core laboratory, collection trays are sent via the automated line to individual phlebotomy stations. When the collection tray arrives at a phlebotomy station, the phlebotomist then calls the patient and collects the specimens. Without leaving the col-

lection station, the phlebotomist then puts the collection tray on an automated line which transports it directly to the specimen processing area in the main lab.

The second automated phlebotomy system is designed to support phlebotomy being done throughout the hospital. It also receives patient test requests. For each patient, the information is confirmed, then the automated system prints and applies bar code labels to the tubes and other supplies needed for that patient's collection. A single patient's collection supplies are then sealed in a plastic bag which is sent, via pneumatic tubes, to the specific site in the hospital where the phlebotomist can retrieve it, perform the collection, then send the pre-labeled specimens back to the lab.

A second noteworthy example of automation in specimen collection at the University of Tokyo Hospital laboratory is a fully-automated urinalysis line. To my knowledge, nothing like this exists in a laboratory in the United States. This urinalysis line was remarkable to watch in operation.

At the main specimen collection center (located adjacent to the core laboratory) exist several urine collection rooms for patients, each with a toilet and sink. Every urine collection room has a pass-through window that opens directly into the laboratory. The patient takes his/her filled paper cup, opens the pass-through door, and places the filled cup of urine directly into the automated transport system.

Urine Specimen Transport

To accommodate this, UTH has designed "hocky puck" carriers on the automated line to hold the cup of urine (which contains approximately six to eight ounces of fluid). Once placed on the automated line, the urine specimen begins its journey. As it reaches the specimen prep station, a pipette extracts the urine specimen and loads it into the analyzer.

What happens next is actually quite entertaining. The specimen cup travels to a station where a robotic arm lifts the cup from its carrier puck. The robotic arm next extends over a vitrous china fixture, resembling a toilet. The arm then dumps the specimen into the fixture and a flush of water moves it into the sewer system. The robotic arm then returns the cup to vertical, moves it over a waste hole, and drops it cleanly into the trash receptacle.

This fully-automated urinalysis system was designed by **IDS**. According to Dr. Yokota, the original cost for the entire installation, including facility preparation, automation, and analyzers, was in the range of U.S.$2 million. This system handles about 200 urine specimens per day.

Keen Interest In Automation

Several observations will help lab directors and pathologists in other labs understand both the philosophy and the investment in automated support for phlebotomy and a fully-automated urinalysis system as described above.

One, total laboratory automation (TLA) was first installed at the UTH lab in 1990. The lab is now in its fourth generation TLA system. Efforts to automate phlebotomy only came after lots of effort and investment in automating pre-analytical (specimen processing) and analytical stages.

Thus, once the laboratory had realized productivity gains, reduced the number of errors, and achieved less variability because of automation of pre-analytical and analytical stages, lab managers next focused on the remaining largest source of lab errors and variation in work processes. That logically led them upstream of specimen processing, into specimen collection, phlebotomy, and specimen transport to the lab.

Two, automation is viewed as a way to achieve similar improvements in productivity, error reduction, and less variability in collecting and handling specimens before they are received by the laboratory. Automating as much of the specimen collection and transport process as possible is

Tokyo University Hospital Uses Automation for Specimen Collection In Phlebotomy & Urinanalysis

Photo 1: This shows the automated phlebotomy system that prepares specimen collection supplies and transports them directly to the phlebotomy stations, which are in an L-shape counter, starting at the left of the instrument and running in the upper left of the photo.

Photo 2: This shows how close the phlebotomy stations are to the main laboratory. Phlebotomy draw stations are at left. One section of the automated line that leads to pre-analytical stations and the analyzers is at right.

Photo 3: Editor Robert Michel stands next to the automated collection supply prep instrument, the Techno Medica BC-Robo-585. In his hand is a sealed bag of specimen collection supplies made to order for a specific patient's blood collection.

Photo 4: This photo shows the automated urine specimen transport line. The puck carriers are at the top. The robot arm is dumping a urine specimen into the vitreous china fixture, where it will be flushed. The hole at the left is where the robot arm will drop the now-empty specimen cups.

therefore a desirable goal. Further, this automation would allow specimens to flow directly into the pre-analytical stages without human intervention, further serving the ideals of total laboratory automation.

Three, the high number of specimen collections done daily (about 2,000 patients and about 9,000 tubes and other types of specimens) at this laboratory site supported the economics of automation. Such high volume means that return on investment (ROI) can be rapid.

By contrast, few hospital laboratories in the United States come close to drawing 2,000 patients per day from captive inpatient and outpatient populations on their medical campus. That means the ROI calculations for this same phlebotomy automation solution would be much different.

My point here is to call attention to the fact that Japanese hospital laboratories are now almost 30 years into total laboratory automation. Relative to hospital laboratories in the United States, Japanese laboratories support a larger daily volume of work and have much more experience with automation than their counterparts in the United States. TDR

Technology Update

Healthcare Has First Standards for Use of Bar Codes and RFID

ANSI and two healthcare groups collaborate to develop standards to support these technologies

THREE ORGANIZATIONS have jointly developed information technology standards to be used in identifying patients, drugs, and medical devices. These standards use bar code, radio frequency identification (RFID), and two-dimensional symbol technologies.

The **American National Standards Institute** (ANSI) recently approved the first part of this new data standard, which is called "Positive Identification for Patient Safety, Part I, Medication Delivery Standard." ANSI worked with the **Health Industry Business Communications Council**, in Phoenix, Arizona, and **Partners HealthCare System**, in Boston, Massachusetts, to jointly develop the standard.

Focus on Patient Safety

In the 239-page document that describes the standard, the developers said, "The scope of this standard is to define the data formats for the data carriers (bar codes, 2-D symbols or RFID tags) which are used to automatically capture information to positively identify objects in the process around medication administration and management. The objects include employee badges, patient wristbands, non-IV medications, IV-medications, smart infusion pumps, and device license plate labeling for intelligent devices."

The proposed system and resulting specification requires the use of barcodes, 2-D symbols, or RFID tags to automatically capture data, thereby reducing transcription or data entry errors and improving patient safety. Without a standard, vendors use different protocols, inhibiting the ability of technologies to communicate with each other.

The U.S. healthcare market for RFID products and systems last year totaled almost $300 million and explosive growth is predicted for this technology over the next five years. In its report "RFID Opportunities in Healthcare in the U.S.," issued last year, market research firm **Kalorama Information**, in Rockville, Maryland, estimates that the healthcare RFID market will reach $1 billion by 2010 and $3.1 billion by 2012.

Kalorama declared that "RFID technologies are dramatically changing many industries, but… the greatest market for RFID is in healthcare. Hospitals, pharmaceutical companies, nursing homes, and other healthcare entities will benefit from using the technologies to keep track of inventories and patients. Growth in RFID in healthcare will occur as issues of network infrastructure, interoperability, and the costs of implementation are resolved."

THE DARK REPORT predicts that RFID will find multiple applications in laboratory medicine, once the price point of RFID chips falls to a more economical level.The **Mayo Clinic** already uses RFID to tag specimens moving between its gastroenterology surgery suites and the histopathology laboratory. *(See TDR, January 29, 2007.)* TDR

Managed Care Update

Cell Phones to be Used to Report Patient Self-Test Results

CareFirst Blue Cross Blue Shield of Maryland ready to launch diabetes management service

HOW ABOUT USING A CELL PHONE to monitor patient in-home laboratory test results? That's about to happen with a new program introduced by **CareFirst Blue Cross Blue Shield of Maryland**.

CareFirst will test whether monitoring devices in cell phones can help patients with diabetes manage their blood glucose, blood pressure, and cholesterol levels. CareFirst is working with **WellDoc Communications** of Baltimore, Maryland, to use WellDoc's web- and cell phone-based diabetes management system, which is designed to help patients optimize their diabetes management.

CareFirst will use the cell phone/WellDoc system in a 12-month clinical trial involving 260 patients with Type 2 diabetes. The primary goal is to evaluate the effectiveness of this system to help reduce patients' blood glucose levels (HbA1c). In an initial study, patients who used the WellDoc system experienced a two-point drop on their average HbA1c level within 90 days of starting the program.

The cell phone-based diabetes management software allows patients to provide data to healthcare professionals in a secure fashion. Also, physicians and other healthcare providers can offer real-time feedback to patients about how to manage their conditions.

"We are excited to provide our members with the ability to better manage their diabetes by utilizing a device they use everyday, their cell phones," said Jon Shematek, M.D., CareFirst's Senior Vice President and Chief Medical Officer. "Our focus is two-fold. First, it is to help patients and providers optimize diabetes management; and second, it's to reduce the costs associated with diabetes care."

Researchers at the **University of Maryland School of Medicine**, under the direction of Charlene Quinn, Ph.D., R.N., will conduct the clinical trial. Quinn is the principal investigator and an Assistant Professor of Epidemiology and Preventive Medicine.

WellDoc claims that its WellDoc system can help improve patient outcomes by reducing a patient's risks of heart attack, stroke, blindness, kidney failure, and other complications. Those improved patient outcomes, in turn, can reduce the cost of care.

Doing Lab Tests At Home

Using cell phones to transmit clinical data is an established technology. What is new is the attempt to use cell phones to aid large numbers of patients with chronic disease do a better job of managing their health. This poses an interesting question for pathologists and lab managers. Will the combination of in-home diagnostic testing and cell phone reporting of results to caregivers eventually encourage certain lab tests now performed in clinical laboratories to shift to patient self-test settings? TDR

CEO Summary: It is always challenging to ensure consistency and high productivity across the different labs in a consolidated lab organization. To help staff focus on quality and efficiency, Alverno Clinical Laboratories LLC uses Lean methods to improve quality and timely delivery of lab results in its regional core laboratory and the labs in the 27 affiliated hospitals in Illinois and Indiana. This strategy helped Alverno save almost $11 million last year while turning out 14 million billable tests.

Management Strategies to Share "Best Practices" Across All Lab Sites

Implementing Best Practices Across 27 Hospital Labs

NOWADAYS, HOSPITAL LABORATORY ADMINISTRATORS AND PATHOLOGISTS responsible for multi-hospital laboratory organizations are faced with several challenges. How should laboratory operations be consolidated and standardized across the different lab sites? Can laboratory "best practices" be introduced into each of the hospital labs in a way that makes the laboratory organization a national leader in operational performance and financial success?

A good place to look for answers to these and other laboratory management questions is **Alverno Clinical Laboratories, LLC**, and **Alverno Provena Hospital Laboratories, Inc.**, headquartered in Hammond, Indiana. This laboratory organization is made up of a competitive, for-profit lab company (Alverno) and 27 hospital laboratories owned by three Catholic healthcare systems.

As one of the nation's largest consolidated and integrated hospital lab organizations, Alverno is notable just for sheer size. Its 27 hospital labs are spread out across Indiana and Illinois. But equally notable are its management achievements.

Data from **Management Insight, Inc.**, a laboratory consultant in Michigan, show that Alverno's collective lab organization has among the best turnaround times among 41 similar consolidated lab operations. Further, Cheryl L. Vance, CEO and President of the Alverno laboratory organization, has documented annual savings of $10.9 million compared with what it would cost to run these 27 hospital labs without the consolidated approach and without emphasizing standardized "best work practices" across all laboratory sites.

One important factor in this success is because Alverno deployed and actively uses Lean and Six Sigma methods in 15 of its 27 hospitals. Another critical success factor is the non-stop management effort to improve communication among the different laboratory facilities. Alverno also uses an innovative charge-back system to fund laboratory operations. It is a particularly effective tool for obtaining capital when laboratory equipment needs are identified.

Merger of Three Systems

All of these results are possible because Alverno gets full support from the three Catholic hospital systems that merged over the past several years to form one of the largest hospital networks in the United States. In 2004, the **Sisters of St. Francis Health Services** (12 hospitals) in Mishawaka, Indiana, merged with **Provena Health** (six hospitals) in Mokena, Illinois. Last year, **Resurrection Health Care**, which runs eight hospitals in greater Chicago, joined the integrated labs. Now Alverno's consolidated laboratory operation manages 36 sites, including 27 hospital labs, the central lab in Hammond, Indiana, and eight patient service centers.

"Last year we did about 8.6 million billable tests," stated Vance. "With the addition of the hospital labs from Resurrection Health Care late last year, we are projecting that number to increase to 14 million billable tests as those laboratories are fully integrated into the Alverno lab organization. We believe our strategy of an integrated lab model is one key reason for our success."

The decision to operate all the hospital laboratories using an integration strategy was decided very early. "Before the two original Catholic health systems (the Sisters of St. Francis Health Services and Provena Health) merged, they undertook a due diligence project to decide if it made sense to put the labs into an integrated lab model for all of the hospitals from both systems," Vance explained.

"At the time, both the Sisters of St. Francis and Provena Health each had an integrated laboratory organization. But internally, each of these two organizations had slowed their progress toward full integration," she added. "Lab integration efforts were almost at a standstill at both health systems at the time of their merger.

"Post-merger, our team of lab managers was held responsible for the implementation

and quickly came to agreement to pursue the strategy of having one large integrated lab to serve both health systems," explained Vance. "The two healthcare systems engaged lab consultants to investigate that laboratory business model, identify the potential cost savings, and evaluate the operational impact such an integration strategy would have on how labs delivered lab testing services.

Proposal Calls for Core Lab

"Following their evaluation, these consultants met with the board of directors and recommended a single, integrated laboratory organization, with one large core lab, to serve the entire system," noted Vance. "Once the board approved that plan, its decision helped bring the administration at each hospital into support for the laboratory integration strategy.

"In addition to Lean, we use many other management tools," Vance explained. "We've always used the plan-do-study-act (PDSA) tool and have trained laboratorians in Six Sigma as well."

"This support by the board and the individual hospital administrators was a key reason our lab integration program advanced rapidly," recalled Vance. "Another factor that speeded the process was that we had an existing core lab, located relatively centrally, that was already built and had adequate capacity.

"In addition, it was our firm belief that most efficiency comes from a single location without building duplicate administrative space," she added. "Further, with labs at many locations, there is the challenge of tracking specimens and handling add-on tests. Since we support a 24/7 lab operation that serves many different clinical sites, we intentionally wanted to concentrate testing at a central site.

"In this first integration phase, we speedily implemented an acute care services lab at each of the 18 hospitals," Vance noted. "The balance of clinical testing, along with microbiology, was performed at the core laboratory in Hammond, Indiana. All of this lab integration work was achieved in one year; during 2005.

"Once that major integration of lab testing across the 18 hospitals was achieved, our strategic focus then shifted to seeking the economies of scale inherent in such a consolidated laboratory model," she continued. "As currently structured, each of our 27 hospital laboratories performs about 70% of the inpatient and outpatient specimens originating at that site. Specimens that do not need an immediate result are referred to the core laboratory, as is all molecular testing and microbiology testing.

"Next, with 27 hospital labs stretched across two states, we quickly recognized the importance of having consistent work practices in each lab facility," observed Vance. "At the time of the Provena/St. Francis merger, three Provena hospital laboratories were actively implementing Lean quality management methods. It was clear from the early results generated by Lean that we should move rapidly to introduce Lean methods into the other hospital laboratories. To date, we have Lean procedures now running at 15 of our 27 hospital labs.

"In addition to Lean, we use many other management tools," Vance explained. "We've always used the plan-do-study-act (PDSA) tool and have trained laboratorians in Six Sigma as well. We find that Lean helps eliminate waste, which then allows us to use Six Sigma to improve the process.

"As with any new operational approach, introducing Lean methods to laboratory staff can be both complicated and challenging," noted Vance. "But the Lean introduction goes well, in part because we did it differently than most organizations do. It would be too costly to have a consultant

At-A-Glance | Alverno Clinical Laboratories, LLC

Core Laboratory: Hammond, IN

Participating Labs:

- Sisters of St. Francis Health Services (12 hospitals)
- Provena Health (6 hospitals)
- Resurrection Health Care (8 hospitals)

Annual Test Volume: 14 million

Outreach Volume: $13 million

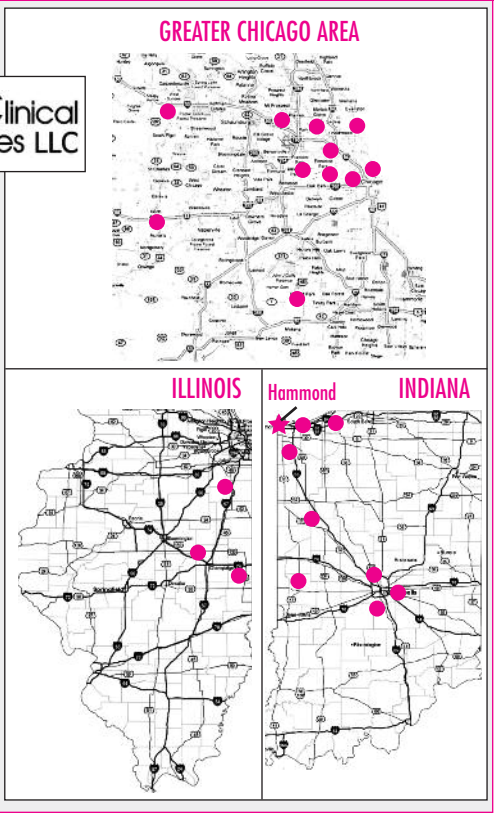
Pathologists: 55

Employees: 1,600

Web Site: **www.alvernoclinicallabs.org**

Now one of the nation's largest regional hospital laboratory organizations, Alverno Clinical Laboratories, LLC, includes a regional core laboratory, 27 hospital laboratories, and a network of patient service centers in both Indiana and Illinois.

The maps at right show the location of the Alverno Core Laboratory in Hammond, Indiana and most of the 27 hospital laboratories located throughout Indiana and Illinois.



instruct the staff in each of 27 hospital labs on how to use Lean methods.

"To make Lean part of our intrinsic operations, we brought in a consultant to do a 'train-the-trainer' process at one of our sites," commented Vance. "As these individuals become knowledgeable and proficient in Lean methods, they were moved to other departments and other laboratory sites, where they trained colleagues. Now, within the Alverno laboratory organization, we have a surprisingly deep pool of skilled Lean practitioners.

"In parallel to this effort with Lean, during the past year, we expanded our quality department," Vance said. "We started by sending three system quality directors to the **University of Michigan School of Engineering** Lean program. Now, those three people in the organization are certified in Lean tools and techniques. Thus, our strategy was to use Lean consultants to develop our own skills in Lean management, then use these skills to train a growing number of staff members.

"This all happened with the full support from our hospital administrators," she added. "They recognized the value of using Lean to reduce variation and have consistent quality and service at all of the locations. They knew that consistency and quality generates savings.

"Since introducing Lean, we have standardized our processes and showed those lab sites that have not yet implemented Lean the value of improving our metrics

in several areas. In particular, we do well in lowering turnaround time (TAT), improving service levels provided to our emergency department, and conducting morning draws.

"Reducing variation and having consistent service levels helped us produce other impressive results," Vance continued. "Significantly, the added productivity allows us to reduce staffing through attrition or by reassignment to higher value services within the lab.

"By using Lean to create a uniform work flow across all laboratories, we've realized substantial benefit from standardizing equipment platforms in hematology, chemistry, and immunology at all locations," she said. "Another benefit of standardized equipment and using Lean work flow is that we can now more easily move staff as needed among different lab facilities to support leaves or vacations.

Flexible Staff by Design

"Over the next year or so, we plan to train a pool of technologists or technicians to be able to work in any of our facilities instead of just one. Then we will use this pool of staff (who would agree upfront) to move from lab location to lab location as needed.

"We know from our own internal work with models of productivity specifically in technical areas, that our staff productivity is very high compared with similar operations in other labs," Vance explained. "Our productivity metrics are used to identify best practices at different lab sites and compare this performance to other sites. Where we spot the opportunity for improvement, we send in a Lean team to help that lab's staff identify opportunities to improve and further standardize work flow by incorporating Alverno's internally developed 'best practices' techniques.

"All this work on staff productivity helps us to operate efficiently," she added. "For example, in 2005, when the two organizations came together, we were projected to have reductions of 34.5 full-time equivalent (FTE) staff. As it turned out, we were able to accomplish almost all of those reductions through attrition. We started with 1,198 employees in 2005 and added more lab facilities when Resurrection Health merged with us in December. Now we have 1,600 employees, but have maintained increased productivity across this larger number of lab sites.

More In-House Testing

"Another benefit from our Lean implementation is an expanded in-house lab test menu," stated Vance. "In the 30 months since the September 2005 formation of our integrated laboratory organization, we have introduced more than 120 new assays, performed at the core lab facility. This has reduced the cost of send-out testing while improving the turnaround time for reporting results to ordering clinicians.

"Collectively, these management strategies helped us save almost $11 million as of the end of last year," Vance commented. "These savings are based on the original projections the consultants gave us when Alverno's integrated laboratory organization was formed. It was estimated that, by the end of year two, savings from lab consolidation and standardization would total $3 million. The actual savings were $10.9 million at the end of 2007, paired with measured increases in the service performance of our different laboratory sites.

"We have documentation that our labs' service metrics to other clinical departments are among the best in the nation," continued Vance. "Consultant Thomas Joseph of Management Insight, Inc., was asked to evaluate our turnaround times for emergency department testing for troponin and for our morning draw testing.

"He compared our performance to that of 42 other hospitals that similarly

utilize a core lab model like us," she commented. "Almost across the board, our hospital labs were in the upper quartile. So, we are doing something right. For our labs to be among the best performers when benchmarked against other external integrated labs was significant. Our board of directors was very pleased to learn that information.

"One significant challenge we face every day is having a consistent management approach in each facility," Vance continued. "Of course, Lean helps us address that problem, but obviously, communication is critical when you have so many labs over such a large area. To ensure that communication is getting down to all levels, we have a monthly newsletter and quarterly town hall meetings with all staff. Also, we conduct one-day meetings with all site leaders every month.

"We know from our own internal work with models of productivity specifically in technical areas, that our staff productivity is very high compared with similar operations in other labs," Vance explained.

"Alverno also had a system quality team of three directors who are Lean certified," she added. "Often one of these three individuals heads up the quality or best-practice initiatives. We also use our monthly site leader meetings to share ideas and improved processes. These are ways that we disseminate our best practices throughout our laboratory system.

Pillars of Service Identified

"Further, during training and development and in every staff evaluation, we hold staff accountable for their results," Vance continued. "Each lab department sets goals and objectives each year, then managers help every staff member hit his or her targets. Another step we take is to look for the most qualified individuals to move into leadership positions. Having seniority or good clinical skills is not an automatic qualification to be an effective leader.

"We also manage to the core values of our health system, which works well. We emphasize the pillars of service that the board has identified," observed Vance. "Those pillars are service, quality, stewardship, people, and growth. Under each pillar, we aim for continuously improved outcomes.

"Under quality, for example," noted Vance, "a staff member would indicate that he or she has made a commitment for TAT for ED and for morning draws. Under stewardship, we would aim to show productivity increased as compared with other sites or we would show how each facility is performing, relative to its budgets and compared with the organization's budget.

"Given that we have so many labs over such a large area, it was important to have a consistent management approach in each facility," Vance continued. "But also, because we're such a new organization, we can prioritize our standards and establish timelines that other, older organizations may struggle to implement. When we made the decision to have standardized equipment, that triggered standardization, wherever possible, for all of our policies and procedures as well. And, we take full advantage of the ability to standardize whenever we can."

THE DARK REPORT observes that Alverno clearly is using all the tools available to optimize efficiency. Lean methods have helped the company standardize operations across 27 hospitals in two states. Lean makes it easier to ensure that each lab follows the same processes. Alverno's success at benchmarking and achieving operational performance that places it in the upper quartile is further validation of this stratregy. **TDR**

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PhyTest Assists Doctors With Lab Testing Revenue

➤Georgia-based company has exclusive focus to help doctors with laboratory testing programs

➤➤CEO SUMMARY: PhyTest, Inc., created a unique business model upon its founding in 1998. It primarily specializes in handling laboratory test billing and collection services to office-based physicians. It also provides evaluation, consulting, and implementation services to help physicians in client-bill states establish discounted billing relationships with reference laboratories. To avoid Stark Law issues on physician self-referral, these arrangements do not involve laboratory testing done for patients covered by Medicare or other federal health programs.

BASED IN ATLANTA, GEORGIA, **PhyTest, Inc.** is a physician service organization that is uniquely focused on helping office-based physicians manage several aspects of laboratory testing services provided to the patients of its client physicians.

The company was founded in 1998 and provides services to physicians practicing in the states of Georgia, North Carolina, Texas, Tennessee, and Ohio. "We provide specialized billing and collection services to physician practices, limited to diagnostic tests for non-government program patients," stated PhyTest CEO Wade McKenzie. "Lab testing requires expertise and resources that are different than those required for other aspects of physician practice billing. It is difficult for each physician practice to maintain a sufficient level of in-house expertise in this area, so we provide that skill and experience."

PhyTest works with physicians in states that allow discounted client billing for laboratory test services. "Our clients are physician practices," noted McKenzie. "We have a sophisticated understanding about all aspects of laboratory testing. PhyTest can thus generate increased efficiencies in billing and collections for lab test services. Further, we support their in-house test cost management and we assist in their negotiations of lab test prices with reference laboratories."

➤Serving Office-Based Doctors

PhyTest has thus cleverly developed a market niche in helping physicians in client-bill states establish contracts with reference laboratories that allow them to capture revenue from the laboratory tests generated by its patient referrals. Federal health programs, including Medicare and Medicaid, are not covered by these relationships.

PhyTest helps interested physicians evaluate their existing arrangements for laboratory testing to determine which strategies could maximize service and revenue. "Our clients experience differing benefits from our services, depending on whether they previously were performing these functions in-house, or on how efficient they were when they performed these services in-house," explained McKenzie. "The net revenue to the physician group is all of the revenue it gets for the tests it provides to its patients and for which it bills.

"Depending on the size and type of medical practice, and average revenue per test, the revenue per physician for lab tests can vary widely," he said. "Of course, from their revenues the physicians have to pay their practice overhead, which includes paying for the tests and for our services."

For new clients, PhyTest evaluates the physician group's current situation and helps to implement the new business plan for laboratory testing. PhyTest then provides billing and collection services as an ongoing service, being paid a standard percentage of the lab testing revenues collected. PhyTest does not charge a fee for the initial evaluation unless the analysis is exceptionally difficult or extensive.

PhyTest often works with its physician group clients to establish discounted lab test billing accounts with reference laboratories. Although physician group contracts are kept separate from each other and are not linked in any way, PhyTest believes that its familiarity with the laboratories and its systems for facilitating billing can result in favorable discounts from the interested reference laboratory providers for its physician group clients.

Each Group Bills Uniquely

PhyTest has each physician group establish a corporate limited liability corporation (LLC), acquire a provider number, and establish its own bank account. Each LLC will individually bill private payers and patients for laboratory testing services and will deposit the resulting reimbursement payments into its own corporate account. As noted earlier, PhyTest then provides the billing and collection services for each participating physician group.

PhyTest is careful to avoid the federal Stark Laws and anti-kickback laws governing physician self-referral. That is one reason these reference laboratory relationships exclude testing done for patients covered by federal health programs, including Medicare. It has a legal opinion from the law firm of **King & Spalding** in Atlanta, Georgia, which describes how the contractual relationship between the participating physicians and their reference laboratories complies with an exception in the Stark Laws that addresses physician self referral issues involving lab tests.

McKenzie discussed this point. "There is no potential problem, as long as test pricing is not used to pay for Medicare test referrals," he stated. "Our clients just negotiate the best price [from a referral laboratory] they can get, often with our assistance, but they never bring Medicare referrals into the discussion or the contracts, and they always remain free to send tests for Medicare patients and for any other patients to any lab they choose—except, of course, where certain managed care contracts require testing for non-Medicare patients to be performed by a specific laboratory."

Office-Based Physicians Use PhyTest to Enhance Lab Services

PHYTEST, INC., IS A FOR-PROFIT CORPORATION formed on May 18, 1998, and headquartered in Atlanta, Georgia. The Chief Executive Officer is Wade McKenzie. The Chief Financial Officer is David Crane. The Sales Director is Jeff White.

On the company's Web site (at *www.phytest.com*), PhyTest says, "We provide physicians with efficient execution of all financial, administrative, and non-clinical aspects of their laboratory services including:

- Complete laboratory service revenue cycle management
- Third-party payer reimbursement monitoring
- Physician staff training
- Laboratory invoice reconciliation
- Analysis of utilization and cost management.

The company is a member of the **Medical Group Management Association** (MGMA) and **Healthcare Billing and Management Association** (HBMA).

There is an interesting perspective on Stark Law and anti-kickback law compliance which is different for PhyTest's client physicians than for laboratories. Most laboratories and physician groups are familiar with OIG (Office of the Inspector General) Opinion 99-13 and similar published comments on Stark Law compliance. One factor a laboratory must evaluate is the relationship of a discounted price it offers a physician to the laboratory's cost to perform that test.

Issue of Lab's Cost Vs. Price

If a laboratory offered a physician pricing for non-Medicare lab tests that is below the laboratory's cost to provide the test with an intent to induce the physician to refer Medicare patient tests—and the laboratory roceeds to bill that physician's Medicare referrals at the full Part B reimbursement, then the laboratory could be guilty of inducement. That is because it intentionally offered below-cost pricing as a way to gain access to the physician's Medicare referrals.

The issue of the lab's cost is not germane to PhyTest's client physicians. So long as the physicians are simply accepting pricing bids from reference laboratories for non-Medicare tests (and do not know the laboratories' costs for those tests) and do not include anything about access to Medicare patient tests in the negotiation or contract, they can argue that, no matter how aggressive the discounts, they have negotiated prices based on market competition among one or more bidding laboratories.

Market Pricing For Tests

McKenzie agreed on this point, stating "regarding costs, Advisory Opinion 99-13 was requested by pathologists running a lab, so they were able to disclose facts to the OIG about their costs. Our physician groups never know what the [bidding] lab's costs are. The negotiations are between unrelated parties at arms' length, in a very competitive marketplace. In our experience, the market cost for tests can vary widely depending on a number of factors including the level of complexity, degree of automation and efficiency of the lab. So the rates that result are definitely fair market value. This may be why the Stark Law exception for purchases of lab services by physicians is so simple and unqualified."

There are apparently a number of commercial laboratory companies that are comfortable with this reading of the Stark Law. PhyTest indicates that multiple laboratory companies are participating in these types of agreements. "We frequently assist our physician group clients with their contracting for tests," McKenzie said. "At present, our clients use over a dozen different laboratories, including all of the major national labs and a number of regional, local, and hospital-based labs. On the other hand, we do not have any laboratories as clients of our company, nor do we have any partnerships, joint ventures, etc., with laboratories."

Billing & Collecting For Labs

With its expertise in laboratory billing and collections, PhyTest is actively looking for laboratories that might be interested in outsourcing those services. "PhyTest has been in discussions with a few local and regional labs to help them with their billing and collections processes," commented McKenzie. "Although we do not currently have any labs as clients, we would welcome the opportunity to work with them in that capacity."

The 10-year track record of growth at PhyTest, Inc., demonstrates that office-based physicians continue to have an ongoing interest in generating revenue from their laboratory test referrals. The discussion presented above deals with Stark Law and anti-kickback law compliance. But there are other interesting compliance aspects to the business model PhyTest has developed. PhyTest and its client physicians also must comply with other federal and state laws., including those governing direct billing, anti-markup, disclosure rules, fee-splitting, and antitrust. TDR

Contact Wade McKenzie at 404-943-0205 or wmckenzie@phytest.com.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Pathologists are key figures in a new movie titled "Pathology." It centers around a newly graduated pathologist, played by Milo Ventimiglia, who, with several pathology interns, become interested in committing the perfect murder—by leaving no clues for detectives and the medical examiner. Released in theaters last month, "Pathology" is not headed for blockbuster status. In the United States, it opened on April 18 in 46 theaters and grossed $54,244 for the weekend. "Pathology" opened on 259 screens in the United Kingdom on April 13 and grossed £313,886 (US$623,859) during its first weekend.

MORE ON: Pathology the Movie

To date, the critics have not been kind to "Pathology." The *Hollywood Reporter* said, "A particularly nasty slice of medical-themed horror… 'Pathology' will best appeal to… people who look up crime-scene photos on the Internet. Bottom line: DOA." Even the horror movie fan site *Horror Asylum* was unflattering, saying, "Sadly, the film tries to be sensationalist at every turn to make up for a lack of depth." THE DARK REPORT observes that this film is unlikely to encourage us to start a movie review section.

MEDICAL JOURNAL HITS MISDIAGNOSIS

Addressing the issue of misdiagnosis, a supplement to the May issue of *The American Journal of Medicine (AJM)* reports that pathologists, radiologists, and dermatologists make diagnostic errors in more than 5% of all cases. Physicians in other fields likely make incorrect diagnoses in about 10% to 15% of cases. *AJM* suggests improvement will come from developing systems to provide physicians with better feedback on errors.

JAPAN'S HEALTH SYSTEM TACKLES PREVENTIVE CARE

Imagine the uproar in the United States if a federal health initiative used waist size as a trigger for a healthcare intervention! That's happening in Japan, where the health system is launching a new program to identify individuals at risk for so-called metabolic syndrome. Males with a waist of 85 centimeters or larger (33.46 inches) and females with a waist of 90 centimeters or larger (35.53 inches), once identified, will undergo blood tests and have their blood pressure measured. If two of three measures are found to be high (high blood sugar level, high blood pressure, high lipid levels), these individuals will be required to receive counseling by public health nurses and will be asked to make lifestyle changes.

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Clinical Laboratory and Pathology News/Trends

DARK DAILY UPDATE

Have you caught the latest e-briefings from DARK Daily? If so, then you'd know about...

...DARK Daily's visit to the BML laboratory outside of Tokyo, Japan, which services 150,000 patients per day and requires only three med techs to perform 60,000 chemistry panels nightly!

You can get the free DARK Daily e-briefings by signing up at www.darkdaily.com.

That's all the insider intelligence for this report. Look for the next briefing on Monday, May 27, 2008.

Back by Demand!

Lab Quality Confab

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September 24-25, 2008
Hilton Atlanta
Atlanta, Georgia

Two days devoted exclusively to quality management techniques!
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Lessons from Innovative Labs • Access Experts, Vendors, Products
Exhibition Hall & New Products

It's everything about quality and management in clinical laboratories and pathology groups!

For updates and program details, visit www.labqualityconfab.com

UPCOMING...

- ***First Report from the Executive War College: Surprising Developments in Lab/Path Management!***
- ***Who Owns the Patient Specimen? Courts Take a Fresh Look at This Important Legal Issue.***
- ***Laboratory Mergers & Acquisitions and Why New Buyers Are Targeting Lab Testing Market.***

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