



From the Desk of R. Lewis Dark...

THE RED DARK REPORT

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

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COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher



Hospital and Health System Labs Brace for Change

BY THE TIME MOST OF YOU ARE READING THIS, it is likely that the Supreme Court ruling on the challenge to the Accountable Care Act (ACA) will be public knowledge. It was this week of June 25-June 29 that the ruling was expected to be announced.

Obviously, there are three potential rulings:

- 1) to allow the Accountable Care Act to stand as enacted;
- 2) to invalidate the entire ACA on constitutional grounds as argued during the hearings; or,
- 3) to invalidate selected portions of the law, most likely to include invalidating the controversial requirement of the “individual mandate.”

What I would like to put forth to you today is that, regardless of the decision, passage of this legislation has already set in motion transformational forces that will not be greatly affected if the Supreme Court invalidates some or all of the Accountable Care Act. Take the example of some larger payers. Just days ago, **UnitedHealth**, **Aetna**, and **Humana** told journalists that they intend to keep some of the popular elements of ACA. These include offering preventive services without co-pay requirements, covering children on the parents’ policies until age 26, and the elimination of lifetime benefit caps, to name a few.

As I see it, a Supreme Court ruling invalidating the entire ACA will not stop the formation of accountable care organizations (ACO) nor the momentum to more tightly integrate the delivery and management of healthcare to patients. It is equally true that such a court ruling will not derail nor delay the federal program to incentivize hospitals and physicians to adopt and use electronic health record (EHR) systems.

Assume that my prognostications are accurate. What does this mean for hospital laboratory administrators and pathologists? There is plenty of evidence that our healthcare system is already embarked on a transformation that will not be derailed. These pages have discussed all the trends in great detail—ranging from proactive and personalized care to the tighter integration of care delivery and healthcare informatics. Thus, for my money, pathologists and lab managers should continue to anticipate more change and position their laboratory organizations to add the kind of value that is rewarded with ample reimbursement. That is the path to sustained clinical and financial success.

Well-Funded Buyers Put Hospital Labs in Bull's-Eye

➤ **Two new lab management companies want to do deals with hospitals and health systems**

➤➤ **CEO SUMMARY:** *In less than 12 months, two big private equity firms have each launched a lab company with the goal of acquiring and/or managing the clinical labs of hospitals and health systems. In the case of aLabs, it has signed one laboratory management services contract with Aurora and Advocate health systems and another similar contract with Sharp HealthCare. Regional Diagnostic Laboratories says it expects to complete two or three hospital lab outreach acquisitions this year.*

IN THE PAST 12 MONTHS, two companies, each with very deep pockets, have been formed specifically to acquire and/or manage the clinical laboratories of hospitals and health systems.

It marks a significant new development in the hospital laboratory marketplace. Economic conditions in healthcare are changing such that Wall Street investors believe there is a major opportunity to make money by running the labs of hospitals better than the hospitals run their labs themselves.

First out of the gate was a company named **aLabs**. (See pages 5-6.) It was created by **Accretive LLC**, of New York, New York, which is a private equity firm. In its short life, aLabs has signed two major contracts.

The first contract is with **Aurora Health Care** (Milwaukee, Wisconsin) and

Advocate Health Care (Chicago, Illinois) to provide “significant management services” to **ACL Laboratories**, which is the combined inpatient/outreach laboratory organization jointly owned by Aurora and Advocate.

aLabs’ second agreement is with **Sharp HealthCare** of San Diego, California. It is believed that each of the respective lab services contracts between aLabs and these health systems took effect on January 1, 2012.

It didn’t take long before **Accretive** and **aLabs** had a competitor in this newly-created niche market. On May 1, 2012, **Warburg Pincus**, another private equity firm based in New York City, announced the formation of **Regional Diagnostic Laboratories, Inc.** (RDX), based in Brentwood, Tennessee. (See pages 7-9.)

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Regional Diagnostic Laboratories can be expected to have credibility with hospital and health system administrators. Some of that credibility will come from the fact that it has a credit line of up to \$250 million to use in acquiring hospital laboratory outreach programs.

As reported in this issue of THE DARK REPORT, the CEO of RDX expects to complete between two and three acquisitions of hospital laboratory outreach programs before the end of the year.

This is an important element in the RDX story. It is not likely that Warburg Pincus would have committed the funds necessary to create the company and hire executives without a high degree of confidence that it would have at least one or two sizeable hospital lab outreach acquisitions completed in coming months.

Further, the creation of these two new laboratory management companies within a short period of time provides evidence that more than a few hospital and health system administrators are willing to consider changing how they own and manage their clinical laboratories.

For lab administrators and hospital-based pathology groups, these developments are not likely to be welcome. It represents one more external factor that complicates how they manage their laboratory organizations in service of their parent hospital and health systems.

► Unwelcome Developments

For example, business development executives from aLabs and RDX will be approaching hospital and health system administrators to express their interest in acquiring and/or managing the clinical laboratory. After such business meetings, lab managers must often defend the operational and financial performance of their labs to their hospital administrators.

Hospital lab administrators and pathologists should keep in mind, however, that it is tough times for their parent institutions. The American healthcare

system is moving forward with several important reforms. Because hospitals are such important clinical service centers in their respective communities, they must respond to these reforms and that takes capital.

► Hospitals Need Capital

In fact, this need for capital is one major reason RDX expects that it can succeed in a strategy of purchasing the laboratory outreach programs of hospitals. RDX executives point out that hospitals require large amounts of capital to acquire physicians' practices, to establish Accountable Care Organizations (ACO), and to implement electronic health record (EHR) systems. Thus, the sale of the laboratory outreach program can provide the selling hospital with substantial amounts of capital.

For its part, aLabs seems to be pitching efficiency and reduced lab costs, achieved by allowing it to manage the laboratory services, develop more outreach business, and handle laboratory billing and collections. This is equally appealing to hospital administrators, since they are seeing overall reimbursement decline and need to actively manage costs in response to lower revenue.

The arrival of aLabs and Regional Diagnostic Laboratories may also create headaches for another group of labs. Now the lab marketplace has added credible competitors who have the resources to bid for any clinical lab organizations that come up for sale. The nation's biggest buyers of lab companies, including **Quest Diagnostics Incorporated**, **Laboratory Corporation of America**, and **Sonic Healthcare, Ltd.**, will have to fend off these new bidders whenever desirable clinical lab organizations come to market.

The passage of time will tell whether aLabs and RDX have the right combination of business strategy and management acumen to succeed. In the meantime, they demonstrate that the lab testing marketplace is still evolving and changing. **TDH**

aLabs Now Manages Labs For Major Health Systems

➤ Created by a venture capital firm, aLabs has agreements in Milwaukee and San Diego

➤➤ **CEO SUMMARY:** *Established with a unique business plan unseen to date in the lab testing industry, aLabs has already entered into laboratory management services contracts with major health systems in Milwaukee and San Diego. This is an impressive start for a newly-formed company that has no prior experience in clinical laboratory operations. aLabs is recruiting an interesting mix of executives. Some hires are coming from outside the lab industry. Others are experienced lab managers.*

EVEN BEFORE IT LAUNCHED OPERATIONS, aLabs had inked agreements with several sizable health systems to provide “laboratory management services.”

These contracts were negotiated and executed with little notice across either the hospital industry or the lab testing industry. Yet both deals involve well-respected health systems and represent an important new development in the laboratory testing marketplace.

aLabs was created by **Accretive, LLC**, a private equity firm located in New York, New York. Its distinguishing characteristic is that it does not want to purchase or acquire lab assets in exchange for cash. Rather, it wants to manage hospital laboratory operations and share the reduced costs and improved operating margins with that lab’s parent institution.

➤ **Aurora and Advocate Pact**

In the midwest, aLabs entered into a contract to provide management services to **ACL Laboratories (ACL)**. This is the lab organization jointly owned by **Aurora Health Care** and **Advocate Health Care**.

This is a major development. Aurora, based in Milwaukee, Wisconsin, has 15 hospitals in its network. Advocate, located in Chicago, Illinois, has 13 hospitals. Both systems have an active laboratory outreach program that is managed by ACL.

The second agreement held by aLabs is with **Sharp HealthCare** of San Diego, California. This laboratory services management contract covers the four acute care hospitals operated by Sharp, along with its outreach lab testing program.

It is believed that both contracts became effective on January 1, 2012. Neither Accretive nor aLabs have issued press releases. Executives at aLabs have regularly declined requests to comment on their new business. For this reason, most lab administrators were not aware of aLabs’ existence, nor the fact that it had successfully negotiated these two contracts. The information provided in this intelligence briefing was assembled from a number of sources, including public records.

As part of aLabs’ business strategy, it has gone outside the traditional clinical laboratory industry to recruit executives

who can bring fresh perspectives to the management and operation of hospital laboratories. This is contrary to the popular wisdom in the lab testing profession, which says that it is essential that experienced laboratory managers and executives be retained to operate a clinical laboratory.

Some examples include John Thomas, who is reported to be Vice President of Lab Operations for aLabs. His previous job was as Executive Vice President of Global Supply Chain Operations for **Hertz**.

In the position of CFO at aLabs is John Adams. He was previously COO at **Axiom** and held positions at **Eclipsys**, **AT&T**, and **Electronic Data Systems Corporation**. The Director of Finance at aLabs is Christopher Hayes. He had previously held several positions at **Accenture**.

► Lab Industry Executives

aLabs has also recruited a number of lab industry executives. Described as a founding director of aLabs is P. Thomas Hirsch. He is credited with being the architect of **Path Lab, Inc.**, based in Portsmouth, New Hampshire.

This successful lab company was owned by several hospitals and provided inpatient and outreach testing services around New Hampshire. After Path Lab's sale to **Laboratory Corporation of America** in 2001, Hirsch started **Laboratory Billing Solutions** and has served as its President since that date.

Other veteran lab executives at aLabs include Rob Albert as aLabs' Vice President and National Lead; Bret Awbrey as Senior Manager, Lab Operations out of San Diego; and Joe McGann, Lab Operations out of Milwaukee.

It is believed that aLabs has not taken an equity interest in the laboratory organizations of its client health systems. Rather, the primary revenue to aLabs will come from sharing in cost reductions achieved by streamlining lab operations and by increased revenue generated from a growing laboratory outreach program.

Accretive's Plan for Hospital Laboratories

IF THE NAME "ACCRETIVE" IS FAMILIAR, it may be because Accretive, LLC, was instrumental in creating **Accretive Health**, now a public company that provides revenue cycle management services to hospitals and health systems.

Accretive's new venture, aLabs, is organized along the business characteristics described by www.VentureBeatProfiles.com as:

Founded in 1999, private equity firm Accretive LLC leads a number of industries by making enduring investments in superior companies. With a long-term approach to ventures, Accretive LLC spends up to several years researching market fundamentals to develop strategy for every individual project.

The experienced team at Accretive LLC does not participate in a business' daily management; instead, Accretive LLC partners provide capital, recruit additional talent, evaluate business opportunities, conduct industry research, and offer strategy and guidance.

Accretive LLC currently features several well-known, robust companies in its portfolio. Among the firms Accretive LLC invests in is Accretive Health, a purpose-built company created by Accretive LLC team members to thrive in its selected industries. Accretive LLC's Accretive Health provides outsourced revenue cycle management to large hospital chains.

If aLabs is operated according to Accretive's past business formula, the longer-term objective is to win enough contract business from the nation's larger hospitals and health systems to make it possible for aLabs to conduct an initial public offering and sell stock to the public. That is how Accretive would be able to realize profits from the venture and pay off its private equity fund investors. **TDR**

New Lab Company Intends To Buy Outreach Labs

➤ **Regional Diagnostic Laboratories wants to acquire outreach lab programs from hospitals**

➤➤ **CEO SUMMARY:** *Based in Brentwood, Tennessee, Regional Diagnostic Laboratories (RDX) says it wants to purchase the laboratory outreach programs of nonprofit community hospitals. RDX is a partnership with Warburg Pincus, a New York investment company. It is a credible buyer and has \$250 million available to fund these acquisitions. Brian Carr, RDX's CEO, predicts that his company may close as many as three lab outreach purchases before the end of this year, based on active negotiations with hospitals.*

THERE'S A NEW LAB COMPANY READY to make its mark in the laboratory testing marketplace. **Regional Diagnostic Laboratories, Inc. (RDX)**, of Brentwood, Tennessee, says it has \$250 million available to use to acquire hospital laboratory outreach programs.

RDX's CEO is serial lab entrepreneur Brian C. Carr. His partner in the new venture is **Warburg Pincus**, an investment firm headquartered in New York City.

The strategic plan for Regional Diagnostic Laboratories is a familiar one—but updated with a fresh twist. According to Carr, RDX will approach not-for-profit hospitals with an offer to purchase all or a majority share of their laboratory outreach business.

➤ **Many Hospitals Need Cash**

Carr thinks hospitals and health systems will be interested in this business proposition because they need cash—and lots of it! “Hospitals today must have access to the substantial amounts of working capital required for them to effectively respond to all the different reforms now occurring within our healthcare system,” noted Carr.

Some hospitals proved quick to be attracted to Carr's business proposal. “Given the talks we are having with different hospital administrators at the moment, we believe that we may be able to announce two different lab outreach acquisitions in coming months, and possibly a third by year end,” he said.

Were that to happen, RDX would be off to a fast start, since there are few examples in the past 25 years of an independent laboratory company purchasing laboratory assets from several different hospitals during the same calendar year.

Timing may be in Carr's favor. “At this moment, a significant number of hospitals are forming accountable care organizations (ACO) and are aggressively acquiring physician practices,” Carr observed. “This requires capital. First, to fund the purchases. Second, to assemble the resources required to operate the ACO.

“At the same time, hospitals and health systems are spending heavily to purchase and deploy electronic medical record (EMR) systems,” continued Carr. “As they implement these EMRs, hospi-

tals must demonstrate compliance with ‘Meaningful Use (MU)’ requirements to qualify for federal incentives.

Carr puts the number of nonprofit hospitals in the United States that have a sizeable outreach program at about 1,000. “And, many of them need capital in areas ranging from physician practice acquisitions to facility expansion campaigns, all in an attempt to remain competitive in a rapidly changing landscape,” he emphasized. “Importantly, many of these health systems don’t consider their outreach labs as ‘core’ to their overall mission.

► Seeking Lab Partners

“When seeking to acquire hospital labs, we call our model the ‘have your cake and eat it too’ approach,” he explained. “I say that because we aim to acquire the laboratory and the outreach program in return for a capital investment and—unlike some of our competitors—we intend to keep and operate those existing lab facilities and assets with the current lab staff.

“Our business plan is to remain in that regional market as a partner with that hospital,” he said. “We will invest our own capital into each acquired lab outreach program with the intent of growing it into a strong local laboratory that serves a region that extends out as far as 200 miles from the hospital and core laboratory location.

“By contrast, most existing hospital lab outreach programs serve an area that doesn’t extend past a 10-mile or a 20-mile radius from their main lab facility,” added Carr. “Post-acquisition, we think we can grow by substantially expanding the surrounding territory that our lab services.

“We consider this an important distinction in our business plan that will be recognized and valued by health systems,” emphasized Carr. “After purchasing each laboratory outreach program, we will continue to operate the lab facility with the existing lab staff to provide local lab testing services within that community.

“This contrasts sharply with the business practices of some lab companies, when—after purchasing a local lab—they ship specimens elsewhere and downsize or reduce staff in that community.

“One recent example is last January’s acquisition of **S.E.D. Medical Laboratories** in Albuquerque, New Mexico, by a major national laboratory company,” he said. “Within months, we understand that the acquirer announced its plans to layoff lab staff and downsize S.E.D.’s facilities and operations.

“This is not what Regional Diagnostic Laboratories will do after it acquires a hospital laboratory outreach program,” explained Carr. “After all, it is the physicians practicing around the campus of these nonprofit community hospitals who will be our primary customers for lab testing services.

“Additionally, nonprofit hospitals tend to have a broader community view of their mission,” continued Carr. “And these hospitals are quite sensitive about any layoffs and downsizing that might occur following their sale of an existing asset, like the sale of the lab outreach program.

“Our proposition is that, by working with RDX, these community hospitals can keep lab testing services local,” he emphasized. “We believe most physicians value a local lab, and, when all other factors—such as price and turnaround time—are equal, physicians prefer to work with a local lab. This is a major reason why we intend to maintain that local presence when we acquire a lab outreach program from a community hospital.

► Three Trump Cards To Play

“In fact, we think we have three trump cards to play that will make us a tough competitor in each local market,” Carr noted. “These trump cards are: 1) to be competitive on price; 2) to offer fast turnaround times; and, 3) to deliver an efficient LIS-to-EMR interface.

“These are essentials for us to win the business of these local doctors,” he said.

Regional Diagnostic Laboratories Brings Together Several Veteran Lab Industry Executives

FOR BRIAN C. CARR, it's déjà vu all over again. The Chairman and CEO of Regional Diagnostics Laboratories, Inc., is once again leading a venture capital-funded start-up laboratory company.

Carr's lab industry career began with **Allied Clinical Laboratories** before it was acquired in 1994 by **National Health Laboratories**. Several years later, he founded **Pathology Consultants of America**. This became **InformDX**, which was acquired by **AmeriPath** in 2000. Carr served as President of AmeriPath.

At the founding of **American Esoteric Laboratories** (AEL) in 2003, Carr was Chairman and CEO. AEL was acquired by **Sonic Healthcare** in 2007. Carr then followed up in 2008 with a new business called

OralDNA Labs. That company was sold to **Quest Diagnostics Incorporated** in 2009.

Among the executives working at RDX are several individuals who worked with Carr at these other lab companies. President and COO of RDX is John G. Mazzei, who worked with Carr at AEL. RDX's Chief Information officer is J. Mark Farrington. He worked with Carr at both OralDNA Laboratories and AEL. Sam Daniel is the Chief Financial Officer at RDX and he also served at OralDNA Laboratories and AEL.

Another notable development with Regional Diagnostic Laboratories is that Haywood Cochrane will serve on its board of directors. Cochrane was CEO of Allied Clinical Laboratories through its sale to NHL in 1994. He has served as a board member on several of Carr's earlier laboratory ventures.

"We want to tap the loyalty physicians have to their local laboratory provider."

Carr emphasized that, in addition to the purchase of a hospital laboratory outreach program, Reference Diagnostic Laboratories is prepared to negotiate other types of lab testing arrangements with community hospitals.

"Our primary strategy is to make an investment to acquire outright a hospital's laboratory and outreach system," he explained. "But we recognized that different community hospitals have different needs. For that reason, we also have an *a la carte* menu.

"For example, if hospital administrators prefer, we can also manage the hospital's inpatient lab for them," noted Carr. "Similarly, if the hospital simply wants management and/or capital to further develop its existing laboratory, we can offer both.

"Of the two potential deals now being negotiated, one multi-hospital health system wants us to manage the inpatient labs for its four hospitals (in addition to also

acquiring the outreach lab). In the second deal, the administrators at this hospital are interested in selling us the outreach laboratory program. Post-sale, they would continue to manage their own inpatient laboratory.

➤ Retaining an Interest

"It is also important to recognize that we are inviting hospitals to take a minority interest in the lab as part of these transactions, if they so desire," explained Carr. "It would allow these hospitals to share in the growth of the outreach business."

Regional Diagnostics Laboratories' war chest of \$250 million can certainly catch the attention of administrators at nonprofit community hospitals. With so many hospitals requiring capital to invest in physician practices, develop ACOs, and acquire EMR systems, RDX's business proposition might be the right opportunity at the right time.

TDR

—By Joseph Burns

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Real-time business intelligence (BI) guides decisions

Indiana Clinical Lab Taps Data To Improve Service to Doctors

►► **CEO SUMMARY:** *Business intelligence is on the verge of becoming the next “big thing” in clinical laboratory management. Lab teams are using real-time data dashboards to quickly identify problems and take proactive steps to raise service levels to clients. South Bend Medical Foundation says these software systems and related tools are helping it raise the bar on service and quality.*

EVERY CLINICAL LABORATORY is a gold mine of data. There is information in abundance, ranging from patients’ lab test results to the performance of individual analyzers and time stamps on every aspect of pre-analytical, analytical, and post-analytical work processes.

“To be successful moving forward, it will be necessary for labs to unlock the knowledge contained within all this data and use it to inform real-time management decisions,” predicted Bob King, Senior Vice President of **South Bend Medical Foundation (SBMF)**, in South Bend, Indiana. “Tapping this data to extract the knowledge requires the use of new software tools and represents the next

big area of opportunity in the management of clinical labs and pathology groups.”

South Bend Medical Foundation is one of the nation’s first labs to acquire and deploy some of the latest tools in business intelligence (BI). Its lab teams are finding ways to use data that help them deliver levels of lab testing services that were impossible to achieve just a few years ago.

The informatics foundation required to produce business intelligence is what King describes as a “laboratory customer relationship management (LCRM) system. “Within our laboratory, we use software and other tools to present relevant data in real time to pathologists and lab directors,” he stated in his

presentation at the *Executive War College* in New Orleans last month. “We believe that every lab can better utilize real-time data inputs to improve client services in three specific ways.

“First, tools now exist that allow labs to gather several related sets of data and process that data to gain immediate access to client intelligence,” he explained. “For example, at SBMF, we know how many tests clients are submitting at any one time. We can also quickly see whether a client is having problems getting specimens picked up.

“Second, these data give labs what I describe as a ‘360-degree view’ of each client relationship,” said King. “It is the full pic-

ture of all service elements and it allows our lab team to boost sales and service by identifying and solving problems in real time.

“Third, these are the data sets that allow nimble lab organizations to be proactive in sustaining top service to their client physicians,” he noted. “By having this data available through the day, every day, our lab team is able to immediately identify trends. They can then react to those trends before anything develops into a problem for either our clients or our lab.”

South Bend Medical Foundation is a sizable clinical lab organization. “We serve hospital laboratory clients located in the four states of Indiana, Illinois, Ohio, and Michigan,” stated King. “The foundation has 800 employees, including 21 pathologists. It operates 24 hours a day, 365 days per year.

► **Building on Informatics**

“In some of our client hospitals, SBMF is fully responsible for all inpatient and outpatient testing activities,” noted King. “In these settings, SBMF employs the laboratory people, owns the equipment, staffs the pathology departments, and provides all laboratory testing and quality assurance. At other client hospitals that operate their own laboratories, SBMF provides medical directorship of the pathology services.

“In addition to these management arrangements for various hospital clients, SBMF provides reference laboratory services, blood products, and traditional outpatient laboratory services,” he continued. “We are a SAMHSA-Certified Laboratory for forensic toxicology.”

SBMF is also a major participant in the area’s health information exchange (HIE). “We own 50% of the **Michiana Health Information Network**,” said King. “MHIN was established in 1998. It is a health information exchange in South Bend that also has an electronic medical record (EMR) system and houses a data repository.

In 1985, 75% of SBMF’s specimen volume came from four hospital-based laboratories and the remaining 25% came from

office-based physicians,” he explained. “Obviously, much has changed in those 27 years.

► Building Lab Outreach

“Increasing test volume is still a primary driver at our laboratory,” noted King. “At the same time, our strategy is to leverage informatics in ways that directly help us expand our business and develop new outreach clients.

“To achieve these goals, we wanted to gain immediate access to the client intelligence that we know exists within all that information found in a variety of systems,” King said. “After beefing up our lab’s informatics capabilities, we now provide that information to our sales, service, and operations staff so that they have a consistent view of each client relationship.

“Further, we wanted to transition our lab away from being reactive—responding after a problem is identified—to proactive,” he continued. “We are getting better at identifying and addressing issues *before* they turn into problems.

“We call this ‘proactive trend identification’ and we think we are one of the first lab management companies in the nation to do this,” King noted. “A cornerstone of this capability is to acknowledge mistakes and learn from them.

► Learning From Experience

“Such mistakes were embarrassing when we look back on them,” King admitted. “But they were highly instructive because they gave us the road map to improve how we manage information.

“SBMF generates a wide variety of information from multiple systems,” observed King. “We have a laboratory information system (LIS), of course, along with middleware solutions.

“We also have a customer service system—our CRM—where every call is logged as it comes in to our client service department,” commented King. “We average about 1,200 calls a day and each

call is categorized. It might be a client looking for a result. It could be a client requesting a specimen pick-up, a stat, or an add-on test. These are the basic categories of calls.

“Because we log every call, we can go back and look up that information by call, category, date, or other factors,” King continued. “This information informs our studies of service levels, as well as identifies opportunities for us to proactively ‘up the ante’ and improve a client’s service.

“For instance, we can review which accounts call our client service department multiple times a day,” he said. “Those clients might benefit from electronic connectivity. Now we have objective, detailed data upon which to base those decisions and guide our actions.

► Identifying Clients’ Needs

“Our laboratory also has systems for resource scheduling and inventory management,” added King. “This will make it possible, for example, to identify which office-based clients might be using our sterile urine cups for their own urinalysis testing.

“Of course, these examples are just the starting point for the information systems found in our laboratory,” observed King. “The list is substantial.

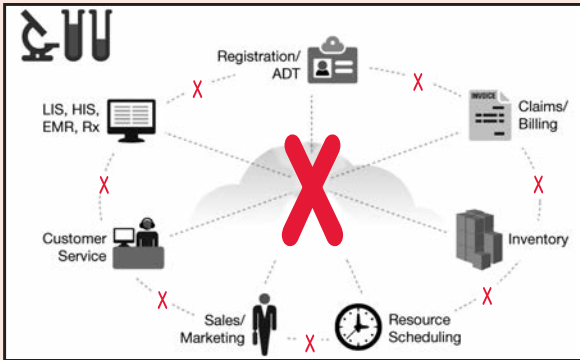
“There are systems for billing, patient registration, courier management, and payroll,” he noted. “Like any other lab, we have Outlook, email, and a customer relationship management (CRM) system.

“Each of these systems is useful, but, because they did not talk to each other, it was impossible for us to move out of the reactive mode I described earlier,” emphasized King. “That was a challenge for us, but there was a bigger problem.

“For a few years, we had a generic CRM that was not specific to laboratory operations and workflow,” he recalled. “We tried to get our people in the field to use this CRM for documentation of their visits.

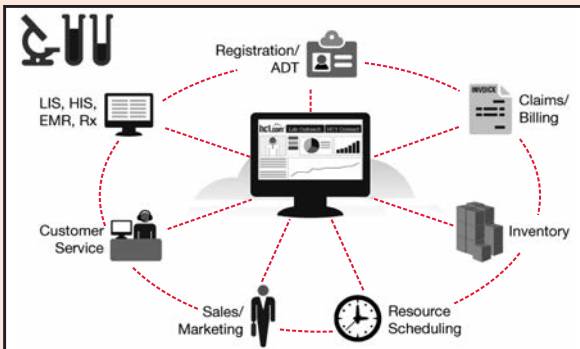
South Bend Lab Organization Uses Informatics To Convert Abundant Data into Intelligence

Challenge: Lack of 360° Degree View of Each Lab Client



At left is a diagram that shows how the multiple and unconnected information systems at South Bend Medical Foundation (SBMF) made it nearly impossible for the laboratory staff, service reps, and sales reps to gain a consistent 360° view of each client.

Solution: Access to 360° Degree View of Each Lab Client



Following installation of a laboratory customer relationship management system (LCRM) at South Bend Medical Foundation and integration of this LCRM with the other informatics solutions within the lab, it became possible to see a real-time, 360° view of each client. Now lab staff and service reps can act proactively to improve client service.

“The system was found to be cumbersome and so the sales staff didn’t use it in the field,” King continued. “When we started looking at a new CRM program designed for use in labs, the sales staff got very excited.

“Made specifically for use in a medical laboratory, this CRM is quick to set up because it already understands lab lingo and lab processes,” he said. “Also, this new CRM allows the reps to use iPads with 3G connectivity.

“This is a benefit for our sales team,” he explained. “Because their mobile devices are always connected via 3G, they can go to a

client site and quickly document their calls and their follow-up actions on the spot.

“The 3G connection has another substantial benefit,” King declared. “Such connectivity allows us to feed all the information that we have in the lab—except the inventory or resource scheduling—to the sales reps in the field.

➤ Access To Real Time Data

“This real-time data access gives our sales and service reps the specific information they need to resolve problems and proactively address important issues while standing in the client’s office.

“There is a staggering range of information that they can access,” he emphasized. “For example, they can view all our logged calls. They can see all clinical laboratory information, all fee schedules, all managed care contracts, as well as the billing and insurance activity associated with a particular client. That allows each sales rep in the field to see if there are any billing or courier problems. They can also view the level of activity from each client, including test volume.

“This is how our business intelligence solution gives us a full, 360-degree view of all client activity and why it can be accessed by people in operations, in sales, and in client services,” he commented. “To further support these activities, we have created management dashboards.

“The tool we use to assemble all of this data and convert it into dashboards is HC1.com,” offered King. “It is sold by **Bostech Corp.**, a company in Zionsville, Indiana, that helps medical labs use technology to improve operational efficiency.

“Now, by client and by individual physician, we are able to track the volume of specimens for each type of test and whether the trend is up or down.”

“The dashboard presents turnaround time, test panel volume, provider order volume, and the sales pipeline, as well as many other kinds of data,” he noted. “Click on any one data component and the dashboard drills down to provide access to the source data.

“A client site visit illustrates why this real-time information is useful,” he related. “One day, I accompanied one of our sales reps on a call to a urologist.

“This urologist was a long-time foundation client and a former board member,” recalled King. “During the

conversation, he said, ‘You probably are here because you want to know why I’m sending all my prostate biopsies to a laboratory in Georgia.’

“At that time, I didn’t know this urologist’s prostate biopsies were going out of state because this information wasn’t showing up on anyone’s radar,” he explained. “From a sales perspective, that urologist’s overall test volume was growing. But the lab system we used at that time did not easily allow us to view test-specific increases or declines.

“That meant there was not a good way for the sales rep or client service rep to recognize that this urologist had significantly reduced his biopsy referrals to our lab over the prior three or four months,” noted King.

► **Tracking Specimen Volume**

“That is no longer the situation today!” he declared. “Now, by client and by individual physician, we are able to track the volume of specimens for each type of test and whether the trend is up or down.

“Best of all, for client retention and client satisfaction purposes, in real time, we can immediately respond to a change in test volume,” emphasized King. “Today, if volume for one test declines sharply, we can visit that physician and have that conversation. And, when we make that call, our team has a complete picture of any service issues or problems that should be discussed with this client.

“These dashboards are equally useful to our lab’s managers,” he continued. “When preparing to meet with finance or our board, I can prepare a detailed picture of our sales pipeline. This information improves the accuracy of predictions of what sales activity will occur during the upcoming two to three months.”

Another use of dashboards at SBMF is to provide clarity when studying lab test turnaround times (TAT) and guiding work flow improvements. “We are able to retire all those TAT reports and spread-

sheets that are so difficult to use,” he said. “We’ve designed dashboards to view, in real time, turnaround times by each test and by individual specimens.

“These dashboards also give us more accuracy and faster access to information in ways that support our client hospitals,” stated King. “The Medicare program is about to require additional reporting on hospital-acquired infections (HAIs). As well, public health departments in our communities regularly want more timely information on infectious disease testing.

“The power of real-time information can be seen in the effort to prevent hospital acquired infections,” he continued. “One of our hospital clients told us that they are using this real-time information to help identify infection patients quickly and prevent the spread of HAIs.

“That’s a great outcome for both the client hospital and our laboratory,” observed King. “It shows how our lab delivers the highest level of service by gaining immediate access to client intelligence, then providing sales, service, and operations with the 360-degree view of the clients’ needs and experiences.

➤ Demand For Information

“In the coming years, clinical laboratories will be asked to provide more information to the physicians and the hospitals they serve,” he noted. “With business intelligence systems like the ones we now use in our own lab, it will be easier and faster for laboratories to turn raw data into useful, actionable information.

“That will directly contribute to lower costs, increased quality, and—most importantly—improved patient outcomes,” concluded King. “As the laboratory industry reaches that point, clinical labs will be delivering real and substantial value to the healthcare system.” **TDR**

—By Joseph Burns

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SBMF Lab Celebrates 100 Years of Service

ONE NOTABLE ATTRIBUTE of South Bend Medical Foundation (SBMF) is that it celebrates its 100th anniversary in 2012! It was founded in 1912 and has operated continuously since that date. Not many clinical lab organizations in the United States share that distinction.

South Bend Medical Foundation runs a sophisticated lab testing operation and is a major regional presence in its service region. “We operate six hospital laboratories and in these labs we also provide the medical director and offer anatomic pathology services,” said Bob King, Senior Vice President at SBF. “In addition, we have nine hospitals where we provide medical directorship and anatomic pathology services.

“For approximately 50 hospitals in Indiana, southwest Michigan, Illinois, and northwest Ohio, we provide reference laboratory services and serve more than 2,000 physicians,” King said. “Of course, SBF has a thriving laboratory outreach program that is served by 11 patient service centers and five rapid response laboratories.

“Blood products, which we provide to 18 hospitals, is a growth area for us,” he continued. “We collect and procure blood and have the infrastructure in place to deliver and to take orders from hospitals for blood products.

“In 2007, SBF procured and moved about 14,000 units,” King said. “This year, we are projected to move 35,000 units, which shows a growth in blood product volume of 150% in five years.”

Long term care (LTC) represents another important testing segment for SBF. “We provide services to 89 extended care facilities,” he stated. “As a community provider offering lab testing services, we believe it is necessary to serve these facilities. This is especially important since the public lab companies walked away from these clients during the 1990s.”

Pathologists Can Offer ‘Companion Informatics’

► Personalized medicine will motivate hospitals to use genetic tests to attract new patients

►► **CEO SUMMARY:** *Community hospitals are recognizing increased interest in personalized medicine among consumers. One expert predicts that this will create opportunities for hospital labs and pathology groups to add value by offering subspecialty expertise in molecular diagnostics, genetic testing, and “companion informatics.” At the University of Louisville School of Medicine, the Department of Pathology and Laboratory Medicine is actively supporting education in these emerging new subspecialties.*

IT IS MUCH EASIER TO PREDICT how the future of laboratory medicine will unfold than it is to establish pathology training programs specifically designed to prepare young pathologists and clinical laboratory scientists for a practice of medicine that does not yet fully exist.

Take the concept of “companion informatics,” for example. Not only does Roland Valdes, Jr., Ph.D., predict that this rapidly-developing field will be essential to the accurate clinical use of companion diagnostics by physicians, but he and his colleagues are developing a focused training program to prepare young pathologists to be experts in this exciting new field of laboratory medicine.

Valdes is Professor of Pathology and Laboratory Medicine and Biochemistry and Molecular Biology at the **University of Louisville School of Medicine**. He is convinced that personalized medicine is about to create powerful new opportunities for hospital laboratories and hospital-based pathology groups.

“Of course, the easy prediction is that acceptance of personalized medicine will

require hospital laboratories to add that expertise to their menu of testing services,” noted Valdes. “However, what pathologists often overlook is that patients—the ultimate consumers—will be playing a greater role in selecting their hospital provider. They are going to prefer using a hospital that has a laboratory capable of performing complex molecular and genetic tests, or at least have ready access to them.

► Evolution Of Lab Medicine

“What is more difficult to predict is how personalized medicine and genetic testing will transform the practice of laboratory medicine as we know it today,” continued Valdes. “In my view, pathologists who have the skills to support this transformation will have the greatest opportunity to add value and be paid appropriately for this value.”

To be specific, Valdes believes that a major change in lab test referral patterns is about to occur. “Today, most community hospitals send out their molecular assays and genetic tests to reference labo-

Responding to Evolution in Lab Medicine, Subspecialty Post-Doctoral Programs Added

REACHING BACK AS FAR AS THE LATE 1980s, the Department of Pathology and Laboratory Medicine at the University of Louisville School of Medicine (ULSM) has instituted new training programs in response to changes unfolding in the field of laboratory medicine.

“Following that post-doc program in clinical chemistry, we added a subspecialty in clinical pharmacogenetics,” recalled Roland Valdes, Jr., Ph.D. Professor of Pathology and Laboratory Medicine and of Biochemistry and Molecular Biology at the ULSM. “Next came a subspecialty in diagnostics proteomics.

“The unique challenge of molecular diagnostics—and pharmacogenetics in particular—is to find a clear, actionable clinical pathway for the application of lab results,” he continued. “That is why, about five years ago, we added diagnostic informatics as a third subspecialty.”

Along with training pathologists and other lab scientists in these subspecialties, the Department of Pathology is involved in collaborations to apply diagnostic informatics and companion informatics to practical solutions that deliver clinical value. “**PGXL Laboratories**, located here in Louisville, is affiliated with the University of Louisville,” said Valdes.

“Earlier this year, we developed our first product from this work at PGXL Laboratory,”

he observed. “However, lab administrators and pathologists in these community hospitals are realizing that there is value in being a local provider of personalized medicine and the lab testing associated with it.

“There is no doubt that pathologists can grow their business by advertising the benefits of personalized medicine to consumers,” he said. “By doing so, hospitals and health systems can increase their census by attracting new patients.

he noted. “It is the PerMIT (personalized medicine interface tool).

“Its use can be illustrated by applications in warfarin therapy,” explained Valdes. “The PerMIT tool pulls together the molecular diagnostic information, the pharmacogenetic information, and the patient data on drug response. With this information, our pathologists and laboratory scientists can give physicians timely and accurate guidance on how to dose for warfarin, which is a difficult drug to use.

“This companion informatics product is moving into broader clinic use,” he continued. “It was in March when **ARUP Laboratories**, located in Salt Lake City, became the first lab to use the PerMIT software to estimate warfarin dosing to stabilize a patient.

“PGXL Laboratories is seeking to develop similar diagnostic informatics tools for use with different drugs and in the treatment of different medical syndromes,” Valdes said. “Cardiovascular medicine is an area of interest, as are oncology and psychiatry.

“There is potential to use companion informatics in identifying treatment for KRAS and other mutations,” concluded Valdes. “There are opportunities in psychiatry to help predict drug response based on a patient’s metabolism, and in pain management to help predict the activation and elimination of pain medications.”

“Today, this is generally seen only in some of the larger institutions, such as the **Mayo Clinic** and those hospitals affiliated with **Vanderbilt University**, among others,” commented Valdes. “But we already see more hospitals recognizing this growth opportunity in personalized medicine. It is why a growing number of hospitals are starting to hire pathologists and laboratory scientists who are certified in the fields of molecular diagnostics and genetic testing, for example.”

This is where Valdes says the field of “companion informatics” is poised to provide great opportunity for pathologists and laboratory scientists. In fact, his pathology department was so committed to this belief that, eight years ago, it established one of the nation’s first training programs in pharmacogenetics and diagnostic informatics.

“The term ‘companion diagnostics’ has been around a long time,” noted Valdes. “These are assays intended to assist physicians in making treatment decisions for their patients. Their particular function is to assess the efficacy and/or safety of a specific drug for the patient.

► Actionable Information

“We recently introduced the term ‘companion informatics’ to describe the coupling of molecular diagnostic information with informatics in order to provide actionable information to physicians about which medications to use and what size dose would be appropriate,” he explained.

“Informatics, meaning both diagnostic informatics and companion informatics, are literally transforming the discipline of laboratory medicine,” emphasized Valdes. “We coined this term in response to what we are observing to be the needs of our hospital clients.

“These hospitals tell us they need help in the areas of molecular and genetic testing,” he added. “Particular needs are in pharmacogenetics, diagnostic proteomics, and diagnostic informatics.

► Standardized Interpretations

“It is not likely that hospital laboratories will require subspecialists in each of these three fields,” commented Valdes. “Technology will see to that. Ongoing developments in diagnostic informatics and companion informatics will help achieve standardized interpretations.

“With standardized interpretations, pathologists or lab scientists with two different kinds of specialties could handle most of these calls,” he explained. “Keep

in mind that, today, most of this work is done in large reference labs, such as ARUP Laboratories and Mayo Medical Laboratories. But eventually smaller hospital labs will do this work routinely because the equipment to perform this testing is becoming cheaper, less complex to operate, and more accurate.”

In his experience dealing with community hospitals, Valdes believes that personalized medicine will not only be used by hospitals to attract patients, but personalized medicine also has the potential to remake lab medicine into one of the most important specialty practices within the hospital.

“Today pharmaceutical therapies are critically important,” he noted. “But there are signs that diagnostics could eventually trump pharmaceutical therapeutics, primarily because test results will determine the most efficient treatment course and efficiency of any drug before therapy is applied.

► Guidance By Pathologists

“Under this new paradigm, guidance by pathologists and laboratory scientists is critical for efficacy and improved patient outcomes, not to mention reducing the overall cost of the healthcare encounter,” observed Valdes. “In my view, the future of laboratory medicine lies in progressive interpretation of novel testing modalities.

“This will be most obvious in the use of molecular diagnostics as a companion diagnostic test,” said Valdes. “As this occurs, the subspecialty field of companion informatics will be one way that hospital labs can deliver more value to physicians and patients.”

The experience of the laboratory at the ULSM provides an interesting window into the awareness of community hospitals that their respective laboratories should be acquiring this subspecialty expertise in molecular diagnostics. **TDR**

—Joseph Burns
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INTELLIGENCE

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



Earlier this month, the clinical laboratory at **Ohio State University Wexner Medical Center** (OSUWMC) was sent a letter by federal CLIA (Clinical Laboratory Improvement Act) officials declaring that the laboratory was in violation of proficiency testing (PT) regulations. The OSUWMC laboratory faces two sanctions. One is revocation of its CLIA license. The second is cancellation of the lab's approval to receive Medicare payments. The OSUWMC laboratory has 60 days from the June 11 imposition to appeal the determination to revoke the laboratory's CLIA certificate.

»» **MORE ON: OSU Lab**

Officials at OSUWMC released the following statement: "This letter from CMS constitutes only a notification of a potential action against The Ohio State Wexner Medical Center's laboratory. The Ohio State Wexner Medical Center intends to provide additional information to CMS as part of the process of appealing against

the potential action. Once CMS reviews this additional information, Ohio State is confident that the government's concerns will be addressed." Clients and regular readers of THE DARK REPORT will recall that a growing number of clinical laboratories are finding themselves ensnared in the conflicting language of CLIA requirements as they pertain to proficiency testing. Moreover, federal officials in different regions of the country are handling issues involving PT violations in a different manner. Reports are that the Midwest Region has taken the toughest enforcement actions concerning proficiency testing violations. (See TDR, May 14, 2012.)

»» **BOSTON CHILDREN'S HOSPITAL TO DO GENE SEQUENCING**

Boston Children's Hospital has announced plans to develop and create an "optimized laboratory infrastructure and lab protocols" for next generation gene sequencing that will meet both CLIA and CAP certification stan-

dards. The 395-bed hospital will collaborate with **Life Technologies Corporation** on this project and will use the company's Ion Proton Sequencer. Boston Children's Hospital bills itself as "the world's largest pediatric research enterprise" and describes its agreement with Life Technologies as a "research and development collaboration to develop an end-to-end genetic sequencing lab workflow."



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