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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

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COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Community Labs Arrive at a Crossroads

TODAY, COMMUNITY LABORATORIES ARE FACING THEIR TOUGHEST TIMES EVER. My definition of a community lab includes independent clinical lab companies, hospital lab outreach programs, and pathology groups serving community hospitals.

Never before have community laboratories had to deal with so many discrete market trends and financial setbacks as have surfaced in the past 36 months. I am concerned about the ability of community laboratories to survive and maintain their independence and their ability to be an essential and valuable local resource to the physicians and patients that they serve in cities and towns throughout the nation. Multiple market trends are hammering community laboratories today.

For example, it is more difficult for community labs to retain access to patients. In recent years, health insurers have deliberately begun to narrow their lab provider networks specifically to exclude community laboratories, while favoring national lab companies. Changes to the Blue Card program and **Aetna's** wholesale purge of community labs from its provider networks are two painful examples of this trend.

It is also more difficult for community labs to get payment from private payers for their lab testing services. THE DARK REPORT is hearing regularly from local labs about how different health insurers are ignoring claims, arbitrarily paying claims in a manner different than called for by the patient's health insurance plan, and using similar techniques to avoid issuing payment as specified by state law, by provider contract, and by the individual health insurance plan requirements.

These are powerful trends initiated by the private health insurers. Meanwhile, the Medicare and Medicaid programs have implemented regular cuts to lab test prices, accompanied by more restrictive coverage guidelines. The price reductions made to certain anatomic pathology technical and professional services have been particularly painful to independent pathology group practices.

Add to these market trends the threat posed by the clinical integration that is taking place in the form of ACOs and medical homes. This is why I believe that community labs have arrived at a critical crossroads. Without the right education and lobbying campaigns directed at lawmakers, physicians, and patients, the lab testing industry may be on a path that ends up as a national duopoly. TDR

Speakers in New Orleans Offer Important Insights

Sessions revealed an interesting mix of trends for both clinical labs & anatomic pathology groups

CEO SUMMARY: In coming years, there will be multiple challenges and opportunities for the nation's clinical laboratories and pathology groups. That was one common theme heard from the 90 speakers and panelists at the 19th annual* Executive War College on Laboratory and Pathology Management *that took place on April 29-30 in New Orleans. Lab managers will need to manage in a more proactive manner to keep their labs at the forefront of innovation.

PLENTY OF CHALLENGES AND OPPORTUNITIES lie ahead for clinical laboratories and anatomic pathology groups. That was one theme that emerged from this year's *Executive War College on Laboratory and Pathology Management*.

The message from the leaders of successful laboratories was that opportunities still exist to increase specimen volume and revenue, but laboratory managers will need to work harder to achieve those growth goals in today's tough healthcare marketplace.

In addition to this news, there was a sober assessment of the newly-enacted "Protecting Access to Medicare Act" (PAMA). One section of the law defines how Medicare officials will use market data to set prices for the Part B Clinical Laboratory Fee Schedule (CLFS).

Attendees at the *Executive War College* learned why, beginning in 2017, the federal **Centers for Medicare and Medicaid Services** will be given the authority under PAMA to slash CLFS prices. Evidence indicates that Medicare officials will probably target the 20 highest volume lab tests for aggressive price cuts.

The *Executive War College* took place on April 29-30 in New Orleans. More than 800 clinical lab executives, pathologists, and practice administrators made this year's conference the biggest in its 19 years of operation.

The theme of opportunity and challenge was established during the opening session. In his presentation, Stan Schofield, President of **NorDx Laboratories** of Scarborough, Maine, presented the "Five Rules and Four Questions that Every Lab

Leader Must Know." NorDx is a lab company owned by **MaineGeneral Health**, a six-hospital health system.

Five Rules For Lab Managers

Schofield listed these five rules as essential for any clinical lab striving to maintain state-of-the-art clinical services in a financially-sustainable manner:

1. Add clients
2. Keep clients
3. Create revenue opportunities
4. Get paid
5. Reduce expenses

These rules may seem basic, but it was a unique twist introduced by Schofield that captured the attention of the audience. "Failure awaits any lab manager that follows these rules in the 'old school' or traditional manner," he warned. "Success depends on using a 'new school' implementation of each rule."

Schofield then explained the old school versus new school approach for each of his five rules. "Take rule number two, which is to keep clients," he said. "Old school implementation was: 1) to have account reps visit clients and provide lunches; 2) conduct an annual business review of each client; 3) provide IT connectivity to the client; and, 4) keep the office staff happy at each client.

New School vs. Old School

"Now compare that with the new school implementation of this rule," noted Schofield. "Today, the innovative lab will: 1) utilize a tailored metrics program to monitor, in real time, the lab's quality and services to clients; 2) issue report cards to clients quarterly that detail the lab's quality and service performance; 3) monitor the patient experience and strive to continually improve patient service; and, 3) participate in all payer agreements between insurers and the lab's parent hospital or health system."

Schofield's message was that successful lab managers are actively managing every aspect of the lab's performance. He or she is prepared to intervene in real time to ensure the full satisfaction of every patient and client physician.

"To keep up with the fast-moving evolution in healthcare, it is essential that every laboratory understand its value proposition and work to add more value," stated Schofield. "Labs are already rich in data. What will make your lab a winner going forward is how your lab team uses data to help physicians order the right test for the right patient at the right time, and at the right cost.

"This is equally true of delivering more value to ACOs, medical homes, and payers," added Schofield. "New school lab management requires managers to be proactive in developing lab test services that physicians and payers recognize as contributing to improved patient outcomes and an overall lower cost per episode of care."

Supporting Integrated Care

Another general session speaker mirrored these same key points. At the **University of Miami Health System** in Miami, Florida, both the clinical laboratory and the anatomic pathology department are focused on supporting integrated clinical care.

"It is timely for lab administrators and pathologist business leaders to recognize how quickly fee-for-service payment will yield in favor of value-based reimbursement," declared Richard J. Cote, M.D., FCRPath, FCAP. "To succeed in this transition, the winning lab must provide value-added lab testing services that the market wants to buy."

Cote is Chairman of the Department of Pathology at the **University of Miami School of Medicine**. "Everyone at this meeting knows that healthcare is evolving away from reactive and acute care," observed Cote. "In its place, healthcare is emphasizing proactive care and wellness. To become one of the winners in the era of integrated care, every lab organization

needs to demonstrate expertise in helping physicians better utilize lab tests, as measured by improved patient outcomes and a smaller spend on lab test dollars associated with specific diagnoses.

"But that does not go far enough," he continued. "Labs serving ACOs, medical homes, and other integrated clinical organizations can add value by mining lab test data and the clinical information in EHRs specifically to identify at-risk patients. This allows physicians to intervene in a timely way and that is a win for the patient, for the physician, and for the payer."

Supporting Integrated Care

Cote was direct in his recommendations to the *Executive War College* audience. "It will soon be true that how your laboratory organization delivers value will define the reimbursement it earns," he said. "In fact, it is already true in many regional markets that the 'perceived value' of the pathology and clinical lab service are driving market share to those labs that support accountable care and at-risk delivery models."

The comments of Schofield and Cote illustrate the wider theme heard consistently from other speakers throughout the conference. There continue to be opportunities for clinical labs to grow, expand their clinic service offerings, and earn adequate reimbursement. But this won't happen unless lab managers are persistent in improving the operational performance of their labs while creating high-value lab testing services.

That covers the good news element affirmed by multiple speakers. The bad news element centered upon certain clauses in the "Protecting Access to Medicare Act." Because this law had only been signed by the president on April 1, the majority of attendees at the *Executive War College* were unaware of the law's significant details.

That is why many attendees were surprised to learn that PAMA is the "single biggest change to the clinical laboratory

New Federal Law Has Potential To Disrupt Lab Marketplace

SEVERAL SPEAKERS at this year's *Executive War College* in New Orleans commented on the potentially disruptive elements of the newly-enacted "Protecting Access to Medicare Act" (PAMA) that had been signed into law just four weeks before this conference.

During his presentation, Robert L. Michel, Editor-In-Chief of THE DARK REPORT, explained how PAMA directs Medicare officials to collect market data on clinical laboratory test prices from labs during 2016. The Medicare program will then use that data to set fees for the Part B Clinical Laboratory Test Schedule (CLFS).

Michel found it significant that Congress had placed a cap on the amount that CMS could reduce the price of any single lab test in any given year, beginning in 2017. "Why would Congress put language in PAMA to cap single test price cuts at a maximum of 10% per year for 2017, 2018, and 2019, then 15% per year for 2020, 2021, and 2022?" he asked. "The probable answer is that Congress did not want CMS to implement its plan to slash the prices for high-volume clinical laboratory tests starting in 2015.

"If it were true that CMS intended to implement substantial cuts to CLFS in 2015, then it makes sense that Congress put language into PAMA that forestalled those intended price cuts in 2015," speculated Michel. "However, even after the requirement that CMS gather market data in 2016, Congress felt that it needed to further constrain CMS by specifying the limits to how much CMS could cut the price of an individual test.

"That is why the PAMA language specifies that CMS cannot cut the price of a specific test by more than 10% in each of 2017, 2018, and 2019," he concluded. "Price cuts in 2020, 2021, and 2022 can be no more than 15% in each of those years."

industry since enactment of CLIA 1988," according to Robert L. Michel. He is the Founder of the *Executive War College* and Editor-in-Chief of THE DARK REPORT. He made that statement in his opening keynote presentation.

"The significant thing about this legislation is its potential to trigger the most radical disruption to the clinical lab testing marketplace in four decades!" declared Michel. "That is due to the sections of PAMA that direct CMS to collect market data on lab test prices, then use that data to establish prices for the Part B Clinical Laboratory Fee Schedule."

"The significant thing about this legislation is its potential to trigger the most radical disruption to the clinical lab testing marketplace in four decades!"

Michel believes that one key to understanding the language of PAMA on market pricing is the report issued to CMS by the **Office of the Inspector General** in June 2013. The report is titled: "Comparing Lab Test Payment Rates: Medicare Could Achieve Substantial Savings."

The OIG used a survey of prices paid by state Medicaid and Federal Employee Health Benefit Plans for lab tests to determine that the Medicare program could save $910 million annually on CLFS payments if it cut the prices for the 20 highest-volume lab tests to the much-lower Medicaid prices.

"What is significant about this finding for the entire clinical laboratory industry is the determination by the OIG that, for the year 2010, these 20 highest-volume clinical lab tests represented 47% of all the Part B CLFS claims processed, and 56% of total CLFS payments," explained Michel.

"The potential for financial disruption on a huge scale exists," he continued. "Assume that, beginning in 2017, CMS slashes the price for each of these 20 high-volume lab tests at the maximum rate allowed under PAMA.

CMS Can Cut CLFS Prices

"Between 2017 and 2022, the law permits CMS to cut the price on a single test by a cumulative 75%," Michel stated. "Imagine the financial carnage that would occur to those independent clinical labs and hospital laboratory outreach programs in cases where their payer mix includes 50% or more of Medicare payments."

To illustrate the potential for deep price cuts to individual tests on the CLFS, Michel used the example of CPT 82025–CBC w/Auto Diff. The OIG noted that, in 2010, the CLFS price for this CPT code was $10.89. However, that price could fall to just $4.89 by the year 2022 if Medicare were to apply the maximum percent price cuts each year to that CPT code."

Michel noted that, since this section of the bill does not take effect until January 1, 2017, the lab industry has more than two years to work with Congress to amend the Protecting Access to Medicare Act in ways that would minimize potential financial disruption to the nation's community labs.

Opportunities vs. Challenges

Lab administrators and pathologists attending this year's *Executive War College* were given a clear mix of advice by the speakers. Yes, opportunities remain to increase specimen volume, revenue, and operating margin. But achieving these goals requires a higher level of commitment and management acumen than ever before.

Meanwhile, because of all the challenges in healthcare today, it is essential for both clinical labs and anatomic pathology groups to manage costs in the lab more efficiently and use process improvement methods to deliver more value to physicians, patients, and payers. TDR

Pathology Consolidation Underway in Washington

This month, two regional super-practices each acquired a smaller private pathology group

CEO SUMMARY: Two regional pathology super-practices have emerged in Washington State. In each case, acquisitions and mergers are fueling the growth of the two large pathology groups. In Western Washington and the Seattle metro, CellNetix is the dominant pathology group, with 53 physicians. The sphere of influence for Incyte Diagnostics and its 40 pathologists is Central and Eastern Washington. Consolidation is happening in Washington because smaller pathology groups lack the capital to compete effectively.

IF CONSOLIDATION OF PRIVATE PATHOLOGY GROUP PRACTICES nationally is underway, then Washington state may be ground zero for this important trend.

In recent weeks, two smaller pathology groups were absorbed by bigger brothers in their respective regions. On May 1, **Incyte Diagnostics** (formerly Incyte Pathology) of Spokane, announced that it had acquired **Medical Center Laboratory** (MCL), a pathology group in Yakima.

Just four days later, on May 5, **CellNetix** of Seattle and **Highline Pathology Associates** (HPA) of Burien announced what they termed a merger.

In recent years, both CellNetix and Incyte have been serial acquirers of smaller pathology groups in the Northwest. In the wake of the HPA merger, CellNetix now has 53 pathologists. Also, it says that it "serves 19 hospitals and large clinics in Washington and Alaska."

Following the purchase of MCL, Incyte now has 40 pathologists and provides anatomic pathology services to 30 hospitals in eastern and southeastern Washington State, Bellevue in western Washington, and northern Idaho. Incyte Diagnostics has medical directorships at 13 hospitals.

Incyte's acquisition of MCL came following the retirement of John Onstad, M.D., who was one of its four pathologists. With the transaction, Incyte Diagnostics acquired a core laboratory in Yakima, along with grossing facilities and support staff in four hospitals in and around Yakima, said Sanjay Logani, M.D., a vice president of Incyte Diagnostics.

Medical Directorships

"In addition, Incyte Diagnostics assumes the medical laboratory directorships in three hospitals that MCL's pathologists previously served and is negotiating with a fourth," stated Gary Gemar, Incyte's COO. "The three facilities are **Yakima Valley Memorial Hospital**, **Yakima Regional Medical and Cardiac Center**, and **Toppenish Community Hospital.** Incyte is negotiating with **Sunnyside Community Hospital**."

Joining Incyte Diagnostics from MCL are Jayanthi Kini, M.D.; Jose D. Masi, M.D.; and Harold H. McCartney, M.D.

"Incyte is following a cautious path because no one is sure how the accountable care model will roll out and how pathology services will be reimbursed," commented Gemar. "We are waiting to see what will happen in 2015 and 2016. In the meantime, like other pathology groups, we are doing our best to cope with whatever downward reimbursement pressure comes each year."

Expanding Statewide

At CellNetix, the merger adds the three pathologists from MCL. They are Kin Ritchie, M.D., Ph.D.; Garret Alcorn, M.D.; and Thomas Dean, M.D. The pathology group will also gain access to **Highline Medical Center**, which is a 154-bed acute care hospital and a 115-bed specialty center. Highline Medical Center is part of the six-hospital **Franciscan Health System**.

The consolidation of smaller pathology groups happening in Washington are mirrored in several other states around the nation. Basically, the smaller groups of five or fewer pathologists that are often involved in these types of mergers and acquisitions must resolve two major issues.

The first problem is to replace a retiring partner by recruiting a young pathologist into the group. However, it is often difficult to attract the right candidate, particularly to rural communities.

The second problem is access to capital. Smaller pathology groups are confronted with the need to invest more in information technology to stay linked to their hospitals and office-based physician clients. At the same time, the expansion of the pathology test menu to include molecular and genetic tests is expensive, since the pathology group must buy the necessary instrument systems.

Third Issue For Path Groups

"You can add a third major issue to that list," observed Incyte's Logani. "Within the pathology profession, many consolidations are being done in part because there is so much downward reimbursement pressure on smaller pathology groups. Payment from the government has taken a nose dive in the last few years and that is driving consolidation.

"At the same time, new molecular tests and personalized medicine are shifting the practice of anatomic pathology," he continued. "Pathology practices in small rural communities find it hard to recruit the pathology specialists they need without aligning with larger groups or with groups affiliated with large hospitals."

Gemar agreed with these points and stated that "our acquisition of MCL is a reflection of those trends. In this case, MCL wanted to replace Dr. Onstad upon his retirement, but it learned that few pathologists want to practice in small rural towns.

"Declining revenue was also an issue," continued Gemar. "For 40 years, MCL had been one of the leading pathology practices in Yakima but the declines in reimbursement in recent years were a problem. MCL saw a further reduction in revenue when a gastroenterology group in Yakima installed an in-office pathology department, causing MCL to lose that specimen volume. These two factors led MCL to start talking with us and those talks led to the acquisition."

Similar Issues At Highline

Similar issues were involved with CellNetix and Highline. "When we merged with Highline Pathology Associates, the three pathologists became part of our professional organization and we took over the technical business and their hospital contracts," explained Donald R. Howard, M.D., Ph.D., CEO and Chairman of CellNetix. "Since our founding in 2005, we've recognized the importance of being larger and consolidated because it gives us economies of scale and the ability to compete."

Consolidation has been a key business strategy at CellNetix. "In 2005, several pathology groups came together to form

one group," said Howard, "Next, in 2007, we opened our own technical laboratory in Seattle.

"Since that time, CellNetix has merged with six or more other pathology practices," he continued. "Generally our model is to merge our practice with another and then share equity in our laboratory.

"We prefer merging as opposed to buying practices because we are completely self-funded and primarily pathologist-owned," added Howard. "We don't have any private equity money to spend on acquiring pathology practices.

Aligns Everyone's Goals

"Another benefit is that the business model we have aligns everyone's goals in the best possible way," he noted. "The pathologists who join our group become equal partners in our professional company and they become shareholders in our laboratory. That's what Drs. Ritchie, Alcorn, and Dean did."

Compared to other medical specialities, the anatomic pathology specialty is late to the practice consolidation game. Virtually all other medical specialists underwent extensive consolidation during the 1990s. This was in response to the capitated, full-risk managed care contracting policies of the gatekeeper HMOs during that decade.

During the 1990s, pathologists in the largest metropolitan markets and smaller cities managed to avoid the widespread consolidation happening in primary care, internal medicine, urology, gasteroenterology, etc. These smaller pathology groups have kept their independence. However, current trends in healthcare make it likely that the era of the independent pathology group practice is coming to an end.

THE DARK REPORT is aware of similar pathology group consolidations taking place in other regions of the United States. As noted above, declining revenue and the inability to replace retiring pathologists are among the most common reasons why smaller pathology groups decide that selling or merging with a larger pathology group in their region is necessary. TDR

—Joseph Burns

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Why One Pathologist Predicts More Group Consolidation

PATHOLOGISTS OUTSIDE OF WASHINGTON are contacting CellNetix to gain insight on how private group practices should best respond to trends of declining reimbursement, narrow payer networks, and the need to invest in information technology and sophisticated molecular diagnostic capabilities.

"We regularly field calls from pathologists in other parts of the country," said Don Howard, M.D., CEO and President of CellNetix. "There is tremendous uncertainly around the country among pathology groups, particularly small and medium-sized groups.

"The future for those groups is unknown," he continued. "I foresee that many pathologists will become employed by hospitals and some pathology groups will be acquired by national companies.

"However, in many regions there will be some pathology groups who do as we have done, which is to form a much bigger group of pathologists," predicted Howard. "Our strategy is to have a large number of subspecialist-pathologists, currently in 25 subspecialty areas. This makes us an essential resource for the hospitals we serve."

"That is true even if a very large hospital can employ 10 or 15 pathologists," he explained. "That institution would find it difficult to employ the number and range of subspecialist-pathologists that we can provide to hospitals every day. There may not be enough subspecialist work for hospitals to hire all of those pathologists. Therefore hospitals find it more economical and practical to contract for that subspecialty work."

New Partnership to Open Clinical Lab in Shanghai

UCLA, Centre to Open Lab in China to Offer High Quality Testing

CEO SUMMARY: To fill the unmet demand for quality clinical laboratory testing in China, a partnership between pathologists at UCLA and Centre Testing International Corp. of Shenzen have built and will operate a lab facility in Shanghai. The new lab will open by late September and will initially provide core lab testing services to pharmaceutical companies, other similar clients, and for clinical trials. The lab will then develop and offer sophisticated molecular, genetic, and next-generation gene sequencing test services for cancer and other diseases.

Last month, a new clinical laboratory partnership for Shanghai, China, was announced involving **UCLA** and **Centre Testing International Corp.** (CTI). The partners have built and will operate a 25,000 square foot clinical lab facility in Shanghai.

This is a milestone development for the laboratory medicine profession in the United States. It brings together two credible partners for the purpose of providing state-of-the-art molecular, genetic, and clinical laboratory tests in the world's most populous nation. *(See TDR, April 28, 2014.)*

UCLA, an internationally known brand in its own right, has a Chinese partner that is equally credible. CTI is a public company traded on the Shenzen stock exchange and generated revenues of US$124.7 million in 2013.

With headquarters in Shenzen, CTI provides product testing, inspection, certification, and consulting services to a wide variety of industries. It operates in China, Taiwan, Hong Kong, Singapore, the United Kingdom, Germany, and North America. CTI's lab testing partnership with UCLA will be its first health-related business.

This is intended to be a for-profit business that performs high-quality, advanced diagnostic testing for physicians and patients in China. As such, this partnership is different from the handful of existing arrangements involving Chinese labs and academic centers in the United States.

At least three collaboration agreements exist between academic center labs in the United States and labs in China. One such agreement calls for **Mayo Clinic** to provide reference testing and similar services to **Wuhan Kindstar Globalgene Technology, Inc.** (2011).

An agreement to provide second-opinion pathology consultations and other support services was initiated between **UPMC** and **KingMed Diagnostics** (2011). A third collaboration also involves second-opinion pathology consultations and training. It was established between UCLA and Hangzhou's **Second Affiliated Hospital Zhejiang University** (2010.)

The Dark Report has conducted site visits to both the pathology department at UCLA and the clinical laboratory and pathology department of the Second Affiliated Hospital Zhejiang University (SAHZU) in Hangzhou. Detailed ebriefings about both site visits and how digital pathology is used to further this clinical collaboration were published in the July 16, 2012, and August 27, 2012, issues of The Dark Report.

➤ Robust Demand For Lab Tests

China's fast-growing economy has created a robust demand for accurate, reliable clinical laboratory testing and anatomic pathology services. At the same time, the healthcare system in China has been challenged to modernize medical facilities and train adequate numbers of physicians to meet this demand.

In fact, it was this gap that pathologists at UCLA recognized as they worked with the pathologists at SAHZU. "In 2010, as we began working closely with the pathologists at the Second Affiliated Hospital, we observed two things," stated Scott Binder, MD, Senior Vice Chair, Pathology and Laboratory Medicine at **UCLA's Geffen School of Medicine** and Director of Pathology Laboratory Services for the UCLA Health System.

"First, their lab lacked the capability to do the more sophisticated tests that were often needed to make an accurate diagnosis," he noted. "Second, because they lacked subspecialist pathology training—a common situation in China—they were unable to interpret the slides for many different types of cancers.

"The pathologists and the lab team at SAHZU were terrific, just as we found everywhere we went in China," observed Binder. "Pathologists and laboratory scientists there are affable, bright, and interested in learning how to make an accurate diagnosis.

"They also are interested in establishing and maintaining close ties to labs here in the United States," he added. "But, for the most

part, pathologists in China don't have the ability to start a new lab.

"That presented us with an opportunity to create such a laboratory resource in that country," said Binder. "However, we recognized that we would have to find the right partner in China to fund this project.

"Our next step was to do what any lab developer would do," he continued. "We hired a consultant to help us assess the business potential for a new lab company. Our choice was **L.E.K. Consulting**, a company that has extensive experience in China and has offices in the United States.

"L.E.K. did a market analysis and drafted a business plan for the proposed new laboratory company," said Binder. "That analysis identified the risks and opportunities of the changing marketplace in China.

"In fact, L.E.K. showed that the market for our planned lab services had strong potential," he stated. "Funding was the next step and I interviewed venture capital firms in Shanghai and in the United States.

"We also considered hiring senior staff, and one of the candidates we interviewed for another executive position happened to have experience developing labs in India and Brazil," commented Binder. "Coincidentally, he had worked with CTI in the past and knew that CTI works with a variety of companies in different industries to ensure quality control so they can sell products worldwide.

Advantageous Collaborator

"In certain respects, CTI is like the **Underwriters' Laboratory** here in the United States," he explained. "This individual introduced us and CTI turned out to be a terrific partner; one that has been an advantageous collaborator for us.

"Many of the staff at CTI have been trained at some of the best technical universities in the United States," he pointed out. "As a result, they understand the need for precise and accurate medical testing. In fact, they had a clinical laboratory license already with a large academic medical center, but that medical center had recently decided not to pursue the lab project. That created an opening for us to step in and be CTI's partner."

According to Binder, the Regents of the University of California moved expeditiously to review the business plan and negotiate the joint venture with CTI.

"We expect the new lab facility in Shanghai will be licensed before the end of September," said Binder. "The next step will be to perform a certain volume of tests to show government officials there is sufficient revenue to be viable. Then we can begin expanding the test menu and preparing for a CAP inspection.

Limited Capability to Start

"At start-up, the lab test menu will be primarly core lab functions, ranging from chemistry, hematology and some immunoassays to flow cytometry and IHC," he said. "The more sophisticated molecular and cytogenetics testing and next-generation gene sequencing will be phased in over time.

"In the beginning, this lab facility will primarily serve pharmaceutical companies and other clients who need that kind of testing," added Binder. "As volume from these sources ramps up, the emphasis of the lab will shift to molecular and cytogenetics testing for advanced cancer diagnostics.

"In fact, my goal for UCLA and the goal of our Chinese partners is to eventually create a joint diagnostic cancer center," declared Binder. "There is strong interest in China in establishing joint diagnostic cancer centers.

"By that I mean we would offer interventional radiology and the radiologists and pathologists would work together to deliver an integrated diagnostic report," he explained. "But this joint diagnostic center will only happen after the lab has established a full menu of advanced diagnostics for cancer and other diseases."

Binder was optimistic about the success of the UCLA/CTI laboratory company

Business Plan Shows Potential for Growth in China's Clinical Laboratory Testing Market

IN CHINA, THE POPULATION is estimated at 1.39 billion, representing about 19.3% of the human race. In addition, this population is becoming more affluent, according to Scott Binder, M.D., Senior Vice Chair, Pathology and Laboratory Medicine at UCLA's Geffen School of Medicine and Director of Pathology Laboratory Services for the UCLA Health System.

Before developing a new clinical laboratory company in Shanghai, UCLA contracted with L.E.K. Consulting to do a market analysis and draft a business plan. The analysis showed that the population was growing and aging and that there was a need for testing to support clinical trials.

"In addition, it showed that there is a huge incidence of cancer in China due to the high rate of smoking and because of environmental pollution," noted Binder. "The report also showed that the Chinese middle class and upper middle class were rising.

"For many years, the upper classes in Chinese societies have gone to Hong Kong and Singapore for their healthcare," he observed. "Now the middle class and the upper middle class—which number in the tens and hundreds of millions of people—have been educating themselves about the need to get the best health care.

"Now, these individuals know that they want high quality care and they do not want an incorrect diagnosis," he said. "They also recognize that high quality pathology services produce accurate lab test results.

"Some people say the middle class is driving a healthcare revolution in China," added Binder. "Consumers increasingly believe they deserve the best healthcare in their own cities and towns. They are no longer willing to travel thousands of miles for quality healthcare, and the government is responding to these demands.

"In its report, L.E.K. also pointed out that the Chinese are very aware of brands," he noted. "In healthcare, for example, Chinese consumers associate quality with brand names such as UCLA, **Stanford**, and **Harvard**. Those names alone confer a certain degree of trust for the Chinese consumer.

"Conversely, the Chinese are not excited about clinical laboratory companies that focus on high volume testing," observed Binder. "The names of public companies in the United States that focus on high-volume testing are not associated with quality in China. Therefore, middle class and upper middle class Chinese have no interest in those companies as a source for their clinical laboratory testing."

because of one basic structural weakness that exists in lab medicine in China.

"The chief limiting factor for establishing high quality clinical laboratories in China that perform complex reference and esoteric testing is the shortage of trained medical technologists and anatomic pathologists," observed Binder. "This is why there is such a huge unmet need for so many different kinds of testing.

"It is very difficult to find high-level trained technologists," he said. "That's why we send some of our techs to China and why we have some of their techs come to train here at UCLA. Before we can operate our proposed joint diagnostic centers in China, we must have the right number of properly-trained technologists."

The increased demand for highly-skilled pathologists is a relatively new phenomenon in China. Binder explained that, "the reason for these shortages of pathologists and med techs in China is that, for many years, pathology has not been highly valued. Pathology has a low profile and it's a low paid profession. Therefore, it doesn't attract much interest among young people entering the medical profession.

"Dermatopathology in China is a good example," he added. "We trained several dermatologists in this subspecialty over the course of a few months by having them work with me at UCLA. It was a challenge because they were unfamiliar with the pathology part of training that is common for pathologists in the United States.

"It's similar in other areas of pathology," he said. "There are not many hematopathologists, neuropathologists, or breast pathologists, for example. Because many more of these subspecialists are needed, we are bringing Chinese pathologists to UCLA for that training.

"It's a similar situation with Chinese medical technologists," added Binder. "They already know what to do in the core lab. What is needed is training in the more advanced techniques of molecular, cytogenetics, and gene sequencing. To do that, these techs must be trained on the job and that takes time, whether it is done here in the United States or in China.

"And that's how all the steps to develop this lab have proceeded" he said. "Each part of the process takes time and effort because it is necessary to build trust. That's the way to do business in China.

"On this point, one of the most significant reasons that this project got done was the work of Dr. Jianyu Rao and Dr. Jiaofi Huang here at UCLA. Both are Mandarin-speaking physicians who were motivated to get this clinical lab company started.

"At the same time, we have a number of Mandarin-speaking med techs working at UCLA," noted Binder. "These individuals were anxious to go to China to work and visit family as well. Sending those techs to China was another way we could build trust.

"Of course when med techs come from China to get training here, they find a large and vibrant Chinese community. They're welcome here and that's another way we can build trust with our colleagues in China." TDR

Nine-Year Journey for UCLA to Develop a Lab In China

IT ACTUALLY TOOK NINE YEARS for pathologists at UCLA to develop the relationships and trust needed in China to create the new laboratory company that will open for business in Shanghai this fall.

In 2005, Scott Binder, M.D., Senior Vice Chair, Pathology and Laboratory Medicine at UCLA's Geffen School of Medicine, made his first trip to China. "I was invited by the leading academic medical center in China to give a talk on skin pathology and then do a microscope session with some of the lab personnel there.

"While touring labs during this trip, it became apparent that most labs in China had adequate space, up-to-date instruments, and staff," recalled Binder. "However, they were not doing much volume in esoteric testing.

"When asked why they weren't doing larger volumes of these tests, they said they couldn't get the processes to work well," he continued. "On subsequent visits, it was clear that hospitals in China have tremendous patient volume, but their labs are relatively inactive because of the shortage of trained subspecialty pathologists and trained specialist technologists.

"When I returned to UCLA, I met with Jianyu Rao, M.D., Professor of Pathology and Laboratory Medicine. He speaks Mandarin Chinese and, because he partly trained there, he helped to make this project a success.

"One of the first problems we identified in China's labs was the need for education and more training for the pathologists and clinical lab staff," noted Binder. "That is why we began to send medical technologists from here to work in China and we had labs in China send pathologists and medical technologists to train here at UCLA."

—Joseph Burns

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One Key to Lab Success Is Daily Performance Metrics

Timely reporting of lab performance data helps labs identify and solve problems early

CEO SUMMARY: Every clinical lab today must deal with the twin challenges of performing an increased volume of tests while being paid less money. That's why a handful of innovative lab organizations now use management information systems with analytics that provide detailed, real-time metrics on all aspects of their lab's business and operations. Instead of reviewing reports weeks after the end of the month, managers in these labs have daily snapshots of their lab's performance.

One reality of today's healthcare marketplace is that clinical laboratories are being asked to perform increased volumes of tests at higher quality while being paid less money.

To meet this challenge, savvy lab managers know they must get better at using metrics to inform the host of operational decisions required to boost the productivity of lab analyzers and lab staff, while reducing overall costs throughout their labs.

But many labs are handicapped in meeting these goals for two reasons. First, the performance metrics they use are typically based on data from weeks or even months earlier. Few labs have performance data from the previous day or week and even fewer labs have real time performance data. Therefore, management of ongoing lab performance is hampered.

Second, external benchmarking is essential once a lab has addressed the basics of its operations and workflow. Benchmarking data from peer labs of similar size helps to identify specific opportunities for process improvement efforts.

This benchmarking data also shows how much additional improvement can be achieved. Another bonus from benchmarking is the ability to network with top performing peers to gain guidance in how to implement best practices.

Timely Access To Metrics

"Timely access to accurate performance metrics is the single biggest requirement for labs wanting to improve performance to best practice levels," stated Thomas P. Joseph MBA, MT(ASCP), Founder, President, and CEO of **Visiun Inc.**, of Ann Arbor, Michigan. "The irony is that, in the majority of clinical laboratories today, only 'dated' performance metrics are available to managers wanting to boost productivity and pursue best practices.

'Let me explain what I mean by dated," he said. "Anytime lab managers review data collected only once per month or even once per week, it's like looking in the rearview mirror at their lab's performance.

"Further, it is often the middle of the next month when lab managers get these reports," Joseph explained. "Therefore,

they are already at least four weeks behind—and maybe as much as six or more weeks behind—the actual events summarized in the metrics of these reports.

Analyzers Monitored Daily

"Let's take the example of monitoring the quality performance of lab analyzers," he said. "Most labs get instrument-specific peer comparisons from the QC material vendors, but this information often comes back six weeks after data submission.

"In today's budget-conscious environment, lab managers and health systems can no longer tolerate allowing a poor performing lab analyzer to continue to run for weeks because this has been shown to lead to unnecessary additional lab testing, other medical procedures, or even incorrect diagnoses," noted Joseph. "Think of the difference the QA/QC function would have in your lab if managers were given detailed data each day about the performance of individual analyzers, using QC data or patient results."

Joseph points out that this is just one valuable use for timely review of performance metrics. "Lab managers must look at key performance metrics every day, yet few labs have the information systems in place that can provide daily metrics," he emphasized.

"Daily metrics must also provide sufficient detail so that managers know exactly when processes are working and when they are not," he continued. "This information is critical to sustain Lean process improvement and the practice of daily management for those labs organized around this management tool."

Timely Performance Metrics

This need for more timely performance metrics and operational data is why a growing number of clinical labs have purchased an analytics solution that gives them real-time data feeds. Such systems use management dashboards and other highly-customizable features to deliver detailed information about the lab's performance in all types of activities, from pre-analytical and analytical operations to quality and customer service.

"Once the laboratory implements such a performance management system, each day managers are able to assess the performance of every shift, even every work cell," observed Joseph. "These systems can determine the required staffing for any laboratory process, by shift and by day of the week."

"This level of detail about performance makes it possible for managers to identify potential problems on all shifts throughout the week," he added. "It becomes much easier to spot bottlenecks in the lab. Even the best processes will fail and cause a backup of specimens if there is not sufficient processing capacity (staff or equipment) for the process.

Daily Assessments

"Similarly, these performance metrics are the basis of discussions to identify the root causes of systemic problems," added Joseph. "Guided by accurate, detailed, and timely metrics, the lab team can quickly develop solutions and implement improvements.

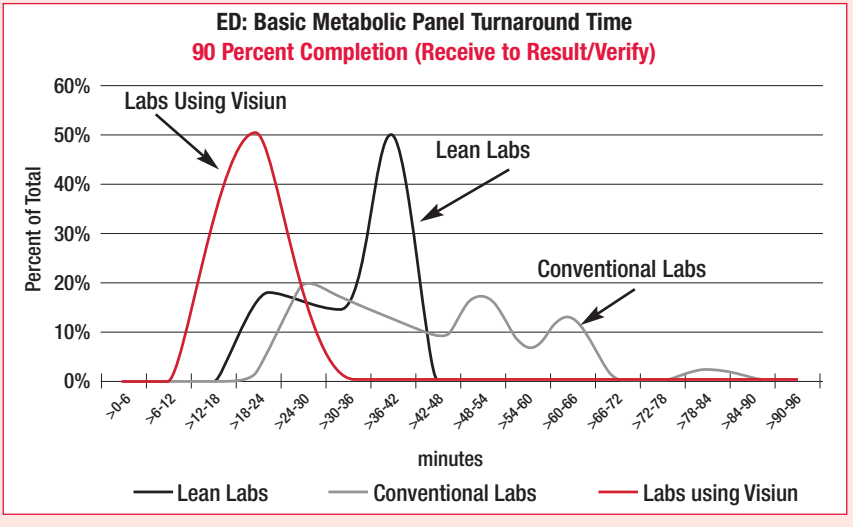
"From experience with our client labs, most managers want to assess performance of all segments of the lab's value stream," he explained. "Not only does this include the lab's internal processes, but also activities external to the lab.

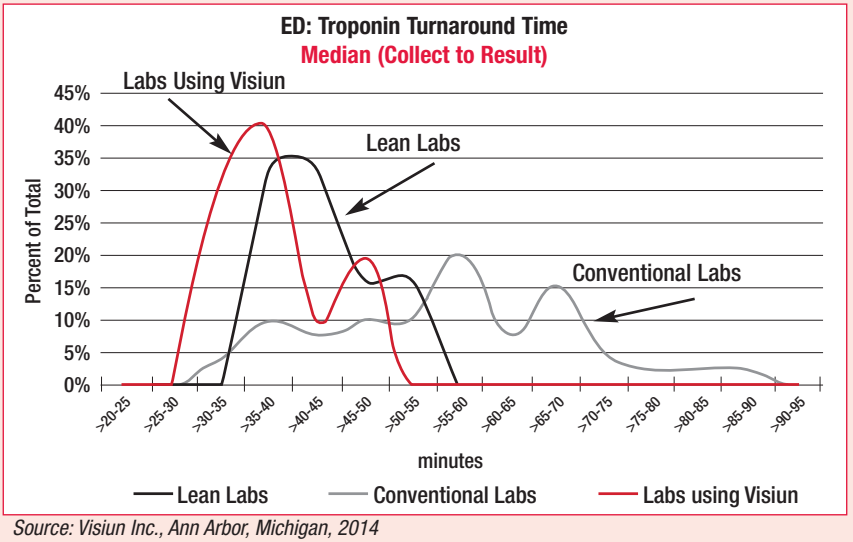
"The best performance management programs collect these data principally from the laboratory information system and from the physician or hospital's electronic health record system," he stated. "Data from these sources allow us to provide metrics from any part of the work flow and at any point in time, such as from the lab test order in the ED to resulting by the lab.

"We have clients that run 600 or more reports on a set schedule so that they can

Real-Time Metrics Guide Lab Managers to Achieve Best Practice Performance in Lab Operations

Each chart below shows the range of performance for clinical labs managed by conventional methods, by Lean, and by use of a daily performance metrics tool. The data was gathered and analyzed by Visiun, Inc., of Ann Arbor, Michigan. Note that, for each measure (median turnaround time for a basic metabolic panel [BMP] and troponin time from collection to result), the Lean labs do better. The labs using Performance Insight to collect and report real-time performance data (Visiun Labs) outperform the Lean labs and the non-Lean labs. One lesson in these charts for perceptive lab managers is how much potential for operational improvement exists when daily and real-time performance metrics tools are used.





Source: Visiun Inc., Ann Arbor, Michigan, 2014

Practical Lessons Learned in How Labs Use Daily Performance Metrics to Improve Operations

ONE FACTOR SEPARATES average performing labs from those with superior performance. That's the observation of someone who helps numerous laboratory organizations with daily management and process improvement.

"When we assess the performance of labs—including traditional (non-Lean) labs and Lean labs—the top performers in both categories share one attribute," declared Thomas P. Joseph MBA, MT(ASCP), President and CEO of Visiun Inc., located in Ann Arbor, Michigan. His company develops and sells Performance Insight, a system that provides detailed analytics performance data for clinical laboratories.

"This attribute is a commitment to performance monitoring, informed by detailed data reported in real time," he said. "These labs are diligent about collecting data on performance and operations and reporting these metrics daily. This information is used to rapidly fix problems. It is also allows the process improvement team to identify opportunities to reduce costs and improve performance on an accelerated timeline.

"When lab leadership is engaged and when the staff operate as a team committed to performance improvement, then processes improve," continued Joseph. "What reinforces this operational culture is the commitment to a daily review of performance data.

"It is as simple as having everyone review performance reports, talk about the results, and share best practices," he stated. "Reports with the daily performance metrics reveal what is working and what is not working in each department, at each analyzer, and for each process.

"A few years ago, THE DARK REPORT asked us to contrast the operational performance of early adopters of Lean with conventional labs, using our database of lab performance metrics," recalled Joseph. "We determined that Lean labs demonstrated dramatically improved performance over labs managed in the conventional manner." *(See TDR, January 21, 2008.)*

"Recently we did a study of data from our lab clients practicing daily management and saw even greater performance improvements over Lean-only labs!" he continued. "I attribute this accomplishment to the fact that, although the early lab adopters of Lean had talented teachers, most of these labs had no tools that provided daily metrics. Thus, they depended on their legacy systems for weekly or monthly reporting. This finding confirms the importance and value of daily metrics in achieving top performance."

review their performance on a daily, weekly, and monthly basis," explained Joseph. "The daily reports go out to different teams in the lab so that they can see their own areas of performance each day. All of this happens automatically, initiated by a one-minute-a-day process.

"This is regular feedback that tells them if they are meeting their targets," he stated. "If they don't hit a target in a particular area, they can go to the detail of the report to see which process is not working and who is running that process. That's powerful information to have every day."

Surprisingly, Lean laboratories gain as much benefit from daily performance metrics as laboratories managed conventionally. "Once a Lean laboratory has a tool that produces daily performance data," concluded Joseph, "it becomes easier to not only sustain the initial gains from the original Lean improvement projects, but this timely reporting of data makes it easier to achieve continuous improvement." **TDR**

—Joseph Burns

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

How about a hospital that doesn't have a medical laboratory but issues lab test reports to patients? This unusual development happened in India recently. *The Free Press Journal* of Mumbai, India, reported earlier this month that government health officials had conducted a surprise inspection of the **City Hospital** at MP Nagar, Bhopal. Inspectors found that, even though the hospital didn't have a medical laboratory, it had issued "pathology reports bearing the seal and signature of a fake doctor." The government agency has directed the hospital to investigate the situation and submit a report of its findings.

ADD TO: *Lab Reports*

Lab professionals with long memories will remember it was a series of *New York Times* stories in 1988 about problems in lab testing in the United States—including the discovery of sink testing by some Pap testing laboratories—that led Congress to pass the Clinical Laboratory Improvement Amendments 1988 (CLIA) law. However, seldom do health regulators in the United States find an example of "dry labbing," such as at the City Hospital in India.

WATER STREET BUYS GERMAN DIAGNOSTICS FIRM

Two familiar players in the lab testing industry were involved in the recent acquisition of **Orgentec Diagnostika**, a specialty diagnostics company based in Mainz, Germany. The purchaser is **Water Street Healthcare Partners** of Chicago, Illinois. Scott Garrett, former CEO of **Beckman Coulter Corporation** and a Senior Operating Partner at Water Street, will be Chairman of Orgentec. Last fall, Water Street Capital exited the anatomic pathology business in the United States by selling **Converge Diagnostics** and **Plus Diagnostics**.

TRANSITIONS

• After leading **Sunquest Information Systems** to nine years of rapid growth in revenue and operating profit, Richard Atkin resigned from his position as President and CEO, effective in May 2014. Prior to joining Sunquest in 2005, Atkin previously held executive positions with **Misys**, **SpaceLabs**, and **Datex-Ohmeda**.

• Matthew J. Hawkins was named as the new President of Sunquest Information Systems. His prior experience includes positions with **Greenway Health**, **Vitera Healthcare Solutions**, **Henry Schein Practice Solutions**, and **McKinsey and Company**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, June 9, 2014.