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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Hospital's Closing Is a Lab Industry Opportunity

NEWS OF THE ORDER by the **New York State Department of Health** (DOH) to close **Peninsula Hospital Center** in Rockaway for at least 30 days because of deficiencies in the hospital laboratory is slowly filtering throughout the clinical laboratory industry. *(See pages 7-10.)*

It was on February 23, 2012, when DOH issued an order for summary action against Peninsula Hospital and Guanghui Kong, M.D., Ph.D., who is shown on the 173-bed hospital's website as "Director, Pathology" and is believed to be the hospital laboratory's Medical Director of record. In the order, DOH wrote that the laboratory's state permit was suspended for 30 days because deficiencies identified during DOH inspections on February 20 and 21 were of such nature that "the public health, safety and welfare is in imminent danger."

This is a significant event. It is uncommon for any state or federal agency to take actions which effectively shut down all or part of a hospital's clinical services due to deficiencies in the laboratory. Because these deficiencies in the lab were a major factor in the decision by the New York DOH to issue a 30-shutdown order, it is important for pathologists and laboratory administrators across the nation to get accurate information as to the circumstances that unfolded within this hospital laboratory.

In my view, this is an opportunity for leaders of the nation's various laboratory associations and societies. To date, press coverage of laboratory deficiencies at Peninsula Hospital Center have not been balanced by interviews with informed experts in laboratory testing and clinical laboratory management. That means the public has been left on its own to assess what risks to patient health were involved in this particular case.

That is why I ask you, dear reader, this question: "Would it not benefit the profession of laboratory medicine if an independent review team comprised of pathologists and laboratory scientists looked into the public facts of the case and issued a public report on its findings?"

I argue that such an independent review would provide the lab industry with a highly useful assessment of the problems within the laboratory of a hospital that was known to be struggling financially. At the same time, it would provide an opportunity for the profession of laboratory medicine to provide the public with an opinion independent of the New York DOH about the deficiencies and their potential to negatively affect patient care and health outcomes. TDR

Today's Lab Test Model Won't Survive Reforms

Doing more testing to drive down unit costs doesn't work when payers cut lab test prices

CEO SUMMARY: For more than three decades, independent lab companies have waxed fat by increasing their respective market share of lab test referrals from office-based physicians. This era is poised to end as growing numbers of office-based physicians begin to practice medicine within an accountable care organization (ACO) or similar new integrated care delivery model, while, at the same time, both government and private payers aggressively push down reimbursement for lab tests.

HOW DOES ANY INDUSTRY RESPOND when its most profitable customers undergo a fundamental and radical change to their business model? The clinical laboratory industry will soon need to answer that question for itself.

That's because, starting in 2012, an extraordinary mix of government and market forces will begin to push the American healthcare system toward very different models of care delivery and reimbursement. The speed with which these changes will take root will catch most clinical labs and anatomic pathology group practices unprepared.

As a consequence, many lab testing organizations will find themselves losing significant amounts of money. They will also lack the management acumen and access to capital required to keep pace with the demands of government health programs, private payers, and providers to perform greater volumes of clinical lab testing at ever-lower prices for this testing.

Unfortunately for independent laboratory testing companies, the one healthcare sector that will transform at the fastest pace is that of the office-based physician. Why will this trigger a financial crisis for independent lab companies?

The answer lies in the one great truth about the market for lab testing services in the United States. Since the early 1980s, the major source of profit for independent lab companies has been the lab test specimens originating in physicians' offices.

Moreover, test referrals from office-based physicians is, itself, a huge market

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SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes THE DARK REPORT plus timely briefings and private teleconferences, is $14.10 per week in the US, $14.90 per week in Canada, $16.05 per week elsewhere (billed semi-annually).

segment. According to *Wikipedia.com*, there are approximately 230,000 office-based physician practices and groups. Almost 90% of the nation's 680,000 physicians see patients in an office setting.

Based on its study of the range of trends and reform initiatives unfolding today within the American health system, THE DARK REPORT predicts that, within the next 36 months, there will be significant erosion in the level of reimbursement paid on lab tests referred by office-based physicians. This will disrupt the reliable profit engine that has fueled the growth and financial success of independent laboratory organizations for more than three decades—reaching back to 1980.

Of course, reductions to reimbursement on the lab tests originating from office-based physicians will not be uniform across all medical specialties and all types of laboratory tests. Some medical specialty testing areas will continue to generate ample reimbursement.

Revenue-Per-Requisition

But what will become evident, over the next 60 months, is that the overall level of reimbursement will decline by a noteworthy amount. This will be true when prices across the full menu of clinical laboratory and molecular assays are aggregated. It means that most of the larger independent labs doing routine testing will see average revenue-per-test and average revenue-per-requisition flatten and begin to decline.

THE DARK REPORT is not alone in its analysis of the financial challenges that lie ahead for independent clinical laboratories and pathology groups. Twice in the last six months, our editor has seen presentations by keen strategic thinkers who conclude that the current business model of laboratory testing in the United States and several other developed nations is unsustainable.

It is essential that pathologists, lab administrators, and industry executives understand the changes now unfolding in the American healthcare system and why they will change—in fundamental ways—how the system utilizes lab testing and reimburses labs for these services. To that end, a special session on this topic will take place on May 1-2, 2012 at the upcoming *Executive War College on Lab and Pathology Management* in New Orleans, Louisiana.

Speakers from two of the world's most respected business strategy consulting firms will discuss the changes that are coming to healthcare and how they will disrupt today's status quo in the lab testing marketplace.

Threat To Business Model

First, from **Boston Consulting Group**, James Tucker will describe the twin vice jaws that threaten the existing business model for independent clinical lab companies. One jaw of the vice is the substantial increase in lab test utilization that is projected due to demographics of an aging population and the increased incidence of chronic disease.

The other jaw of the vice is the expected continual decline in the reimbursement paid by government and private payers for lab test services. As the opposing jaws of this vice come together, many independent labs will have limited options to protect their financial viability.

That is because, under the current business model for independent lab companies, it is higher volumes of testing that generate increased profits due to the economies of scale that contribute to lowering the lab's average cost-per-test.

Statistical Analysis

Tucker will provide the statistical analysis that shows why this business model for lab testing becomes unsustainable when government health plans and private insurers repeatedly cut the price they pay per test.

For those lab companies organized on the fundamental premise that higher volumes generate higher profits (because of

Why Growth Is Slowing at Quest and LabCorp: Analyst Highlights Role of Discounted Prices

MANY PATHOLOGISTS AND LAB ADMINISTRATORS will be interested to learn that some financial analysts on Wall Street are catching on to the negative consequences when lab companies use marginal cost pricing to win new lab test business.

One example is a February 16 web post on **SeekingAlpha.com**, by hedge fund manager Paul Nouri, titled "Investors Should Wait Out Quest and LabCorp." He is one of the first to publicly point out that, after paying some $5 billion to purchase large lab organizations since 2006, neither of the two blood brothers "has shown extraordinary growth" during this time, particularly in revenue and specimen volume.

Nouri further stated that this lack of extraordinary growth "can be attributed to a weak pricing environment and meager organic growth. Since LabCorp undersold Quest on the **UnitedHealth** contract [in 2007], both companies have seen operating margin erosion."

He discussed the strong growth rates of the clinical laboratory testing divisions at **Enzo Life Sciences, Inc.**, and **MedTox Scientific, Inc.** Among other factors, Nouri attributed their rapid increases in market share to "physician discontent in dealing with large firms such as Quest and LabCorp."

"The large labs are comfortable with their position in the market and have significant contracts negotiated with providers [and payers]," noted Nouri. "In any industry, this can lend itself to a sense of complacency."

Debt From Stock Buybacks

He went on to point out that both companies "are saddled with nearly $4 billion in debt after spending over $2 billion to buy back 36.5 million shares over the past three years and making over $1 billion in acquisitions."

In Nouri's view, the two companies face an uphill fight. "Looking at Quest and LabCorp, it's difficult to see how either company will excel in the current environment..." he wrote. Further "...the lab space is an easier space for Medicare to cut [lab test prices] than the aforementioned sectors. First, Quest and LabCorp control more than two-thirds of the non-hospital clinical lab market [read: office-based physicians market]. Lawmakers could feel more comfortable making cuts to what is perceived to be a couple of large players..."

It is a fact of life in the marketplace that when companies use "cheapest price" to win customers, they can generally only hold on to those customers so long as they continually underbid the price of competitors. Once another firm offers price-sensitive customers an even lower price, that customer will rapidly switch loyalties to gain access to those lower prices.

'Meager Organic Growth'

Nouri's observation that the "lack of extraordinary growth" at Quest and LabCorp "can be attributed to a weak pricing environment and meager organic growth" is based on recognition of this business principle. A significant portion of the core routine testing business at both of the two Blood Brothers is highly sensitive to price.

This is true of the managed care contracts with major health insurers that have been negotiated at prices reported to be at 40% or even less than Medicare. It is also true of client-bill accounts in states that allow physicians to mark up lab testing services. In these regional markets, Quest Diagnostics and LabCorp have been aggressive at using deeply-discounted prices to win the specimen referrals from these office-based physicians.

Today, both lab firms must deal with the consequence of their "lowest price" strategy. They know that, if they raise prices on these customers, that business will move to a lower-priced competitor. Meanwhile, as Nouri points out, smaller competing labs that "focus on service" are able to "gain and maintain their client bases"—frequently by taking customers away from Quest Diagnostics and LabCorp.

greater economies of scale), the financial squeeze is obvious. A rapid decline in prices paid for tests at the same time that the lab is hit by greater volumes of these same tests, portends financial disaster.

This will be particularly true for those laboratories that have used deeply-discounted lab test prices as a way to access pull-through business. These labs organized themselves around this business strategy: "more volume = lower costs = greater profit from fee-for-service prices."

McKinsey's Strategic View

The speaker that follows Tucker will describe the macro trends now reshaping the nation's healthcare system. It is Paul Mango from **McKinsey & Company**.

Mango will explain how integration of clinical care and health informatics will take the nation's health system in unexpected directions. He expects that Medicare ACOs are not to be prime players in this story.

Attendees at the *Executive War College* will learn about a host of health reform initiatives led by employers, by private health insurers, and by provider groups, that will unfold at a faster pace than similar Medicare and Medicaid initiatives.

Mango is uniquely qualified to explain how these health reform trends will change the lab testing industry. He was the architect of the **Reference Laboratory Alliance in Pittsburgh** (RLA). This was a regional laboratory network of 40 hospitals that competed successfully for physicians' office business in the mid-1990s, until the creation of competing health systems in Pittsburgh brought an end to the network. *(See TDR, September 25, 1995.)*

Negotiating Lab Contracts

Following Tucker and Mango at this session will be Professor Leslie Burnett, Consultant Pathologist at **Pacific Laboratory Medicine Services** (PaLMS) in Sydney, Australia. Over the past decade, Burnett has been involved at the highest levels in negotiating the national clinical lab/pathology testing contract between the federal government and the lab medicine establishment.

What Australia has that the United States doesn't is accurate data on national utilization of laboratory testing. This data stretches back into the early 1980s. Burnett will show the year-over-year growth in utilization of lab testing that the federal government now considers to be financially unsustainable in coming years.

Next, Burnett will address laboratory workforce challenges in his country. Medical schools and laboratory science training programs in Australia are already failing to deliver the number of pathologists, clinical chemists, and laboratory scientists required to meet the steady increase in lab testing.

This special session at the *Executive War College* is designed to give lab administrators and pathologists the full range of information they need to understand how reforms unfolding in the American healthcare system will change utilization and reimbursement for laboratory tests.

Strategic Thinking

It will be the first public forum that presents the strategic thinking and insights about the clinical lab testing industry that has been shared privately with a number of billion dollar lab companies and *in vitro* diagnostics (IVD) manufacturers.

A key theme here is that the pre-eminence of office-based physicians as the primary source of revenue growth and ample profits for clinical lab organizations over the past three decades is about to end.

It is timely for lab administrators and pathology practice administrators to understand the dynamics of healthcare reform, then prepare an effective strategy to help their lab organizations add value with lab testing services in a financially sustainable manner. **TDR**

NYSDOH Shuts Hospital Lab In Queens, New York

Hospital must stop admitting patients while laboratory has 30 days to address 66 deficiencies

CEO SUMMARY: When the New York State Department of Health closed the laboratory at 173-bed Peninsula Hospital Center in New York City on February 23, it became national news. State inspectors issued a nine-page list of deficiencies in the lab, including problems that could affect patient safety. The result of the order was that all patients requiring lab work needed to be moved out of the hospital, and the hospital could not admit new patients through the emergency department or by physician referral.

DID A WHISTLEBLOWER CALL New York State officials to complain about the conditions in the lab at **Peninsula Hospital Center** in New York City?

That's the way it looks after reading the nine-page list of deficiencies the **New York State Department of Health** (DOH) issued for the 173-bed hospital in the Far Rockaway section of the Borough of Queens. The department sent inspectors to the lab on February 20 and 21. The next day, February 23, the department issued the order to close the laboratory for 30 days.

Lab Permit Suspended

In its press release about the matter, DOH stated that "The New York State Health Commissioner Nirav R. Shah has issued an order of summary action suspending the clinical laboratory permit of Peninsula Hospital in Far Rockaway, Queens, for a period of 30 days. This action was taken after a DOH inspection found that the hospital laboratory failed to meet accepted standards, which put patient safety at risk."

The press release went on to say "Commissioner Shah issued a second summary order directing the hospital to stop admitting new patients, to cancel all surgeries and procedures, to suspend any activities that depend upon laboratory services, and to develop a plan to transfer inpatients to other facilities because the lack of a clinical laboratory at the facility poses a danger and threat to the health of current and future patients."

In response to the DOH order, all patients requiring lab work needed to be moved out of the hospital and the hospital could not admit new patients through the emergency department or by physician referral.

It was an unusual action by a government body. No lab expert interviewed by THE DARK REPORT could recall a hospital being forced to transfer patients out of a facility due to deficiencies in the laboratory.

Services that did not require lab testing remained open at Peninsula Hospital. According to the *Queens Chronicle*, this included radiology and an attached nursing home. The newspaper also noted that the financially-troubled hospital had filed for bankruptcy during 2011.

As of March 6, the hospital was taking steps to reopen. Peninsula spokeswoman Liz Sulik told the newspaper that hospital administrators were developing a plan to remedy the laboratory deficiencies so that they could restore full services.

New Medical Director Likely

"Before the hospital can reopen, the laboratory is likely to need a leadership change in the form of a new medical director—and possibly a new lab administrative director—in order to eliminate the 66 deficiencies the department cited in six specific areas," stated Nora Hess, MBA, MT(ASCP), PMP, Operations Managing Consultant for **Chi Solutions, Inc.**, in Ann Arbor, Michigan. She had reviewed the DOH's order of summary action for THE DARK REPORT.

Hess believes the list of deficiencies reads as if a whistleblower alerted the New York State Department of Health officials about the problems. "For example, on January 1, it is reported that a staff member was working alone in the blood bank and prior to this had only two days of training. That's not something that is identified during an inspection. That's something a whistleblower might report.

"Also, in the list of the lab's deficiencies, there were red flags that the hospital was having financial difficulties," Hess added. "For example, they are using outdated reagents. In some cases, the lab did not have any reagent inventory. To me, that indicates that the lab reagent suppliers may not be shipping additional supplies because of payment concerns. State inspectors also found expired blood plasma and observed workers without enough personal protective equipment for handling lab samples."

Resolving Lab's Problems

"It can be expected that, to resolve these problems in the hospital's laboratory, it will require an infusion of cash and a change in the lab's leadership because it will look as if the current leaders have not been actively ensuring that the laboratory produces quality results," Hess added.

Retaining a new medical director with experience at fixing troubled laboratories is one step, she noted. "This individual must be tough and willing to push for the changes required for the lab to correct these deficiencies and achieve an acceptable level of quality," she said. "A new lab administrative director will probably be needed as well, because these two individuals must work hand in hand."

For two years, Hess worked as interim director at **Maryland General Hospital** in Baltimore after that hospital's lab was cited for deficiencies in how it handled testing patients' specimens for HIV, among other problems. "At Maryland General, we spent the first several months just responding to deficiencies and then a longer period of time ensuring that the corrections were fully implemented," she said. "That is likely what it will take for Peninsula Hospital as well."

Patient Care Issues

Elissa Passiment, Executive Vice President of the **American Society for Clinical Laboratory Science** (ASCLS) in Washington, D.C., commented that the DOH inspectors' report cites a mix of deficiencies. Some involve administrative issues and others could affect patient safety as well.

"The New York State Department of Health is responsible for ensuring that all labs comply with its regulations because the department has exempt status under the Clinical Laboratory Improvement Act (CLIA)," she stated. "Exempt status means CMS will accept the work the department does, such as lab inspections. New York State's lab regulations are known to be equal to or more stringent than those of CLIA.

"At Peninsula Hospital, the biggest concerns definitely were the patient safety issues that the department cited and it was shocking to me that the lab was able to operate for as long as it did," commented Passiment. "The findings raise questions about the availability of the medical director, along

Whistleblower Notifies NY State Dept. of Health About Medical Director Change at Quintiles

WHISTLEBLOWERS AND ALLEGATIONS INVOLVING medical director compliance with the regulations of the New York State Department of Health (DOH) surfaced in another case in the spring of 2011. It involved **Quintiles Laboratories, LTD**, of Marrieta, Georgia.

Through the Freedom of Information Act (FOIA), THE DARK REPORT obtained documents about this case from the DOH. In a communication to the DOH, the whistleblower alleged that the lab's medical director had resigned several weeks prior and that the Quintiles lab was operating 24/7 without a medical director while seeking a replacement. Also, the whistleblower alleged that the lab was testing specimens from New York state.

At that time, Quintiles Laboratories had a permit application pending with the DOH to test patient specimens from New York State.

Medical Director Response

In its investigation, DOH was told by Quintiles management and by the medical director who had resigned that this individual, as an independent contractor, was continuing to function as medical director. This arrangement would continue until Quintiles employed a new medical director.

In response, DOH asked Quintiles to provide information about the on-site work hours of the now-interim medical director. Apparently unsatisfied with the answers Quintiles provided, DOH suspended the pending permit, saying Quintiles could submit a new application once it met DOH requirements. Following this determination, DOH Clinical Laboratory Consultant Thomas Lipinski wrote to the whistleblower:

Your complaint of March 29, 2011, alleging that Quintiles Laboratories, LTD, Marietta, Georgia, was operating without a director or New York State permit, was referred to the Clinical Laboratory Evaluation Program (CLEP)...

An investigation was performed and the results were reviewed thoroughly. Based on this review, we have determined your complaint is substantiated for the laboratory operating without a director. Since the laboratory does not have a New York State qualified director, the laboratory permit became invalid. And Quintiles Laboratories will be required to file a new permit application.

Quintiles disputed this conclusion. "At no time did Quintiles' Marietta facility operate without a medical director," declared Phil Bridges, Quintiles' Director of Corporate Communication, in response to questions from THE DARK REPORT. "In fact, during a transition period, both our outgoing and incoming medical directors were on duty simultaneously."

Bridges stated that a new lab director for the Marietta facility was appointed in April 2011. "This individual has a valid New York State certificate of qualification, which was granted on April 13, and the Quintiles lab operates under a valid NYS Permanent Facility Identifier," he said. "On April 18, Quintiles applied for a new permit and the lab was placed by NYSDOH in 'applied for status.'

"In changing the laboratory director, Quintiles was compliant with the customary process of making such a change and, in accordance with established practice, there was a handover phase so that a qualified registered laboratory director was assigned at all times," added Bridges.

"Quintiles is compliant with NYS requirements for its laboratory in Marietta, we are in compliance with NYS procedures, and we are in good standing at NYS," he said. "The license has never been revoked as a result of any quality issues. There has been no investigation and there have been no violations."

The two cases—involving whistleblowers and allegations of deficiencies in how medical directors meet NYSDOH requirements—should be considered fair warning to medical directors in labs licensed by the NYSDOH. The agency has certainly demonstrated its willingness to address what it views as violations of state regulations regarding the role of medical directors. Whether serious, as with the Peninsula Hospital Center laboratory, or minor, relative to the medical director changeover at Quintiles Laboratories, each case reminds medical directors that regulatory enforcement is tightening.

with the attention to detail paid by that person, other managers in the laboratory, and the hospital's administration. More specifically, CLIA is very clear that the accountability for the overall performance of the laboratory resides in the duties and responsibilities assigned to the medical director."

Lack of Training Cited

The list of deficiencies cited by the inspectors included a lack of staff training, a lack of continuing education for the staff, and a lack of safety training, including training on how to ship infectious materials. Also, no supervisor was onsite in the lab in the evenings, during the night shift, or on weekends and there was no chain of command to provide guidance to staff, the inspectors said.

While the lab's day shift supervisor was knowledgeable about microbiology, the supervisor had no experience or training in other clinical areas of the laboratory, the inspectors claimed.

"The medical director would not do the staff's competency testing. He or she would designate that job to a lab director or some other senior staff member," Passiment added. "However, there is no way that the medical director could have not known that this training was not getting done.

Lesson For Lab Directors

"The lesson for lab directors is very clear," she said. "Every lab needs to have a medical director onsite overseeing lab operations and not just signing off on cases," she stated. "CMS has made this specific point innumerable times. CMS holds the medical director and the lab director responsible for ensuring that any lab fully meets all the standards established in the regulations."

Peninsula Hospital Center is not the only hospital with problems in the laboratory. THE DARK REPORT has learned that, also in New York City, another hospital lab was found deficient by the New York State Department of Health in recent months. In this case, however, the state permitted another hospital organization to oversee the lab testing activities in the subject laboratory. This allowed the parent hospital to remain open and to continue treating patients. TDR

—By Joseph Burns

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State, Federal Lab Laws Can Be Very Different

STATE LAW GIVES THE NEW YORK STATE Department of Health (DOH) different powers to regulate medical laboratories than those powers given to the Centers for Medicare and Medicaid Services (CMS) through the Clinical Laboratory Improvement Amendments (CLIA).

Robert E. Mazer, a lawyer and principal with **Ober Kaler** in Baltimore, Maryland, said the issues involved in the case of Peninsula Hospital Center and its laboratory provide a good example of the need for labs to comply fully with both state and federal laws.

"It is important to recognize that there can be differences in how individual states regulate labs, when compared to federal law," observed Mazer, who is not involved in this case. "For example, the state agency in New York issued an order, effective immediately, suspending laboratory operations at Peninsula Hospital Center. It doesn't appear that CMS has the same authority under CLIA.

"By contrast, absent a court order, CMS is required to give five days notice of imposition of sanctions—even when the deficiencies pose immediate jeopardy," explained Mazer. "Theoretically, this five-day notice might provide a hospital with the opportunity to make arrangements with another laboratory, thus eliminating the need to suspend hospital activities. That was not the case in New York, as state health regulators decided to close the lab immediately and without advance notice."

QMS Helps Ontario Labs Cut Errors, Improve TAT

ISO 15189's Quality Management System (QMS) supports continuous improvement to lab services

CEO SUMMARY: In Brampton and Etobicoke, Ontario, the hospital laboratories of William Osler Health System are using the quality management system of ISO 15189 to stay ahead of two powerful trends. Combining the QMS with Lean methods allows the labs' management and staff to continuously improve performance in four important dimensions: decreasing turnaround times, reducing or eliminating the systemic source of errors, boosting productivity of lab staff, and reducing costs across the laboratory.

EACH YEAR, THERE IS MORE PRESSURE on clinical laboratories to improve patient safety, reduce errors, and increase the quality of lab testing. In parallel with these developments, government health programs want more transparency in laboratory performance, particularly as it relates to improved quality and reduced errors.

Meanwhile, both the public and the media are holding clinical laboratories and pathology groups to a higher standard. Even though clinical laboratory errors which negatively impact an individual patient's health are infrequent, such episodes often generate national headlines.

QMS Used By ISO 15189

In recognition of these important trends, a small, but intrepid, number of first-mover clinical labs are implementing a quality management system (QMS) into their organizations. Most frequently, they opt to accredit to ISO 15189: Medical Laboratories and the QMS which is embedded within it.

These labs share a common goal. They recognize that the traditional models of laboratory management and operation do not give them the tools they need to meet the ever-tightening standards of modern medicine as well as the changing public expectations of quality and patient safety.

These lab organizations want a management system that allows them to deliberately and continually drive the rate of errors down to zero. They also want a management system that generates objective, real time data that their lab staff can use to continually improve the quality of laboratory testing. ISO 15189 and its QMS meet both of these strategic requirements.

This step should not be taken casually. "When a clinical lab decides to pursue accreditation to ISO 15189, it is making a major commitment that affects every aspect of daily operations within the lab," stated Patricia Burton, MLT, Quality Coordinator, Laboratory, at **Brampton Civic Hospital** in Brampton, Ontario, Canada.

"The QMS within ISO 15189 requires every staff member in the laboratory to think and act differently as they perform

their daily duties," she added. "It can be quite a challenge to train everyone in the lab to handle their work within the specifications of the QMS, but the benefits are significant."

Hospital Labs Adopt QMS

In July 2010, the two hospital laboratories of the **William Osler Health System** in Brampton, Ontario, earned accreditation to ISO 15189. The laboratories are located at the 608-bed **Brampton Civic Hospital** and at the 262-bed **Etobicoke General Hospital**.

"The laboratories in our health system run about four million tests annually," said Burton. "There are approximately 147 lab FTEs, including 13 pathologists. Both hospitals have a core laboratory. Histology, cytology, microbiology, PCR, and flow cytometry are centralized at the Brampton Civic site.

In the 19 months since earning accreditation to ISO 15189, the two labs have produced impressive improvements across a wide range of lab operations. For example, turnaround times for key tests have been shortened. Errors in blood culture contamination and other areas of lab testing have been substantially reduced.

Population To Double

"William Osler Health System is one of Canada's largest community hospital corporations," she noted. "The two-hospital system serves more than 1.3 million residents in the communities just outside of Toronto. Moreover, population in this area is predicted to double by 2020—just eight years from now. That creates a challenge for our laboratory organization.

"We consider accreditation to ISO 15189—and implementation of its QMS—as an important component of our strategy to handle the substantial increases in workload that will accompany this rapid population growth in the coming years," added Burton. "Further, ISO 15189 accreditation is recognized by the public as our labs' commitment to patient safety, and to error reduction.

"Our accreditation to the ISO 15189 standard has established our laboratories as leaders in quality management in our organization and in our communities," added Burton.

"Leadership at Osler laboratories is using the QMS of ISO 15189 as the foundation for giving lab staff the management tools and methods necessary to continuously improve work flow and productivity in the lab," she continued. "By eliminating systemic sources of errors we have raised the overall quality of laboratory testing.

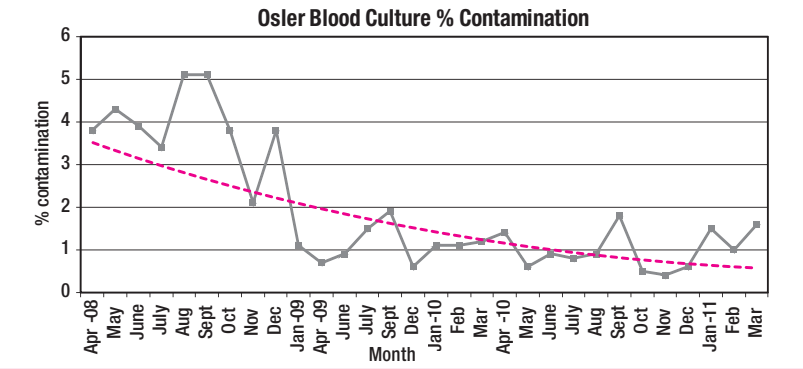
Meeting Lab Challenges

"The lessons from our use of QMS are instructive for labs seeking to increase efficiency and handle increased workload," observed Burton. In November, Burton presented a poster on the labs' QMS results at the *Lab Quality Confab* in San Antonio. The poster won the top prize as the best poster at the conference.

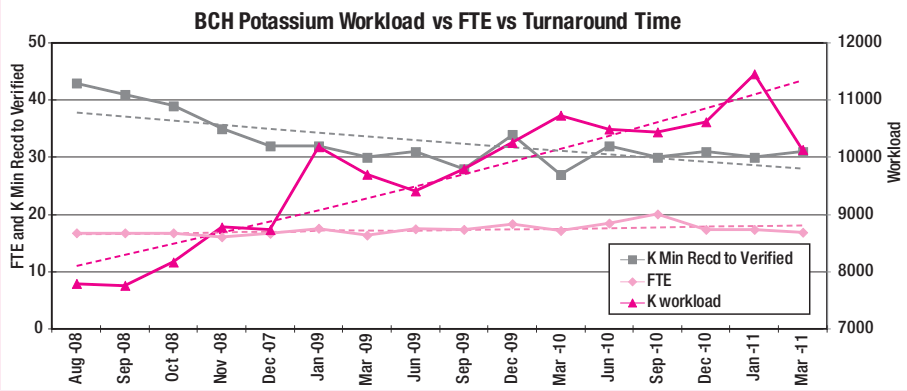
"The Osler laboratories are accredited to the OLA 15189Plus standard of the **Ontario Laboratory Accreditation** (OLA) division of the Province of Ontario's **Quality Management Program-Laboratory Services** (QMP-LS)," Burton said. "This standard is accepted internationally and is based on ISO 15189 and Canadian standards for safety and point-of-care testing. It provides clinical laboratories with the tools needed to standardize processes, address diminishing resources, and set a quality benchmark.

"Our experience to date is that the QMS provides the framework that allows our management and staff to analyze all our operations and various work practices for the purpose of improving the value of our lab testing services," she stated. "In these operational reviews, we involve management, technical leads, and all staff in tracking, reporting, and monitoring processes. We use the Deming cycle plan-do-check-act (PDCA) method.

Guided by the ISO 15189 QMS and Lean Methods, Hospital Labs Achieve Continuous Improvement



IT WAS 2010 WHEN THE TWO HOSPITAL LABS OF THE WILLIAM OSLER HEALTH SYSTEM achieved accreditation to ISO 15189. At this time, one improvement project focused on reducing the rate of blood culture contamination, which was around 4% to 5%. Guided by the QMS of ISO 15189 and Lean methods, the lab team drove that rate down to 1% over the next 24 months. *(See Chart 1 above.)*



ANOTHER IMPROVEMENT PROJECT was directed at reducing turnaround time for potassium testing even as test volume was rapidly increasing. This chart shows that, as potassium test volume climbed by almost 30% in just 48 months, FTEs were held constant, the average turnaround time fell from 43 minutes to 30 minutes, and med tech productivity soared. *(See Chart 2 above.)*

"The results of the QMS review are reported in a quarterly scorecard system for our labs," continued Burton. "Benchmarks are tracked in four key areas related to service quality: service excellence, access, effectiveness, and safety.

"One source of problems we identified through the QMS was errors in the handling, processing, and reporting of surgical pathology specimens," she noted. "In particular, there was an unacceptable level of labeling errors involving histology blocks.

"Because testing surgical pathology specimens is a complex, multi-step process, it involves many staff members and errors can occur at any stage in the process," noted Burton. "These errors can

result in serious clinical outcomes for patients.

"In 2010, we used a failure modes effects analysis (FMEA) procedure to identify potential failures in the handling of pathology specimens," she explained. "The FMEA included these steps: 1) mapping the overall processes for surgical pathology specimens from receipt to report; 2) identifying problems or barriers to ideal efficiency (including the causes of these problems or barriers); and, 3) redesign of existing processes.

"The team reviewed the factors that contribute to errors and devised error-reduction strategies," stated Burton. "This resulted in approval of our business case for the purchase of a patient specimen identification tracking system. We anticipate a significant decrease in errors following implementation of the barcoding system that will replace manual processes for labelling containers, blocks, and slides, a major source of errors."

Contaminated Blood Cultures

Another project focused on reducing errors that contribute to contaminated blood cultures. "The benchmark for blood culture contamination is less than 3% of specimens," state Burton. "In 2008, prior to accreditation to ISO 15189, we were consistently over that level. There were some months when this problem exceeded 5%.

"This was a big opportunity for improvement," she continued. "As lab professionals know, blood culture contamination is a serious problem that can consume substantial health care resources when we have to identify and correct the problem. Clinicians rely on blood culture results to diagnose and monitor febrile patients. Contaminated blood cultures increase patients' length of stay and lead to unnecessary repeated tests and use of antibiotics.

"Through education, the rate of contaminated blood cultures was reduced to less than 3% by early 2009," Burton explained. "Then, guided by our QMS, continuous improvement efforts have lowered that rate to 1% and they have been sustained close to that level for many months now. *(See Figure 1 in sidebar on page 13.)*

Decreasing Turnaround Time

"A third area of concern that is universal in all laboratories is reducing lab test turnaround time (TAT)," she declared. "One issue related to TAT is critical results reporting. These are the results that can lead to patient death or other serious adverse patient outcomes if they are not reported quickly.

"The process improvement team looked at TAT for potassium tests and analyzed TAT versus potassium workload and full-time staff," she said. "In August 2008, it was taking the lab more than 40 minutes from the time a potassium test was received until the result was verified.

"Since then, TAT has been reduced to about 30 minutes each month," Burton noted. "This outcome is remarkable because the number of full-time staff has remained about the same while the volume of potassium tests rose 25%—from about 8,000 per month to about 10,000 per month!" *(See Figure 2 in sidebar on page 13.)*

"We consider this to be an important demonstration of how the QMS helps our hospital laboratories meet the challenges of increased volumes of specimens (from the growing population in our community), even as lab budgets are held constant and we are asked to perform this additional testing with the same number of staff in the lab."

Value Of QMS To Every Lab

These examples demonstrate how adopting a quality management system can give the organization a proven framework and structure that can help it achieve continuous improvement in work processes throughout the laboratory. TDR

—By Joseph Burns

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Dark Index

Quest Diagnostics and LabCorp Report Q-4, Full Year Earnings

Modest gains in revenue, volume, and operating profit reflect some contribution from lab acquisitions

IN RECENT WEEKS, each of the nation's two largest public laboratory companies reported earnings for fourth quarter 2011 and full year 2011. Organic growth at both lab companies continues at low single-digit rates.

This continues the pattern of relatively modest growth that has been posted by each of the two lab behemoths. On the other hand, both lab companies continue to generate significant amounts of cash for their shareholders.

At **Quest Diagnostics Incorporated**, revenue and operating income for Q4-11 was up 3.0% and 10.5%, respectively. Revenue totaled $1.9 billion and operating income was $325.1 million.

For the full year 2011, Quest Diagnostics posted revenue of $7.5 billion, compared to $7.4 billion in 2010. This was an increase of 1.9%. Operating income was $1.3 billion in 2011, versus $995 million in 2010, for an increase of 30.2%.

At **Laboratory Corporation of America**, Q4-11 revenue grew by 5.5% and operating profit for Q4-11 grew by 3.6%. Revenue was $1.4 billion and operating profit was $47.4 million.

Helped by its acquisitions, LabCorp posted revenue growth of 10.8% for the full year 2011, to $5.5 billion, compared to $5.0 billion of revenue in 2010. Operating profit (before adjustments) for the full year 2011 decreased 3.1% from $979 million in 2010 to $948 in 2011.

Quest Diagnostics stated that its acquisitions of **Athena Diagnostics, Inc.**, (closed April, 2011) and **Celera Corporation** (closed May, 2011), contributed 2.2% to its revenue growth during 2011. LabCorp stated that **Genzyme Genetics** (which LabCorp purchased before the end of 2010) contributed 3% to its Q4-2011 revenue growth.

Visits To Doctors' Offices

One aspect of the lab testing marketplace that was closely-watched by financial analysts during 2009, 2010, and into 2011, was the change in patient visits to office-based physicians. During these years, executives from both Quest Diagnostics and LabCorp had commented that quarterly declines in patient visits were one factor in why specimen volume growth at their respective firms was nearly flat, or as reported in some quarters by Quest Diagnostics, even declining. *(See TDR, October 25, 2010.)*

During the Q4-2011 conference calls, there was not much discussion about this aspect of the lab testing market. However, Amanda Murphy CFA, Analyst at **William Blair & Company, LLC**, in her coverage of the Quest Diagnostics earnings report, included a chart that showed, for fourth quarter 2011, patient visits to doctors' offices in the United States increased by about 0.5% over the fourth quarter of 2010. *(See sidebar on page 9.)*

For pathologists and lab administrators competing against the two blood brothers, the conference calls provided useful insights about the primary business strategies and

outcomes for each lab company. Quest Diagnostics, for example, wants to drive revenue growth in three ways.

Quest's Growth Strategy

Its CEO, Surya N. Mohapatra stated to analysts, "As we have said before, our growth strategy is based on three elements: driving innovative new tests and advanced healthcare IT services, enhancing sales effectiveness, and strengthening our relationship with health plans and other payers."

Mohapatra then noted that esoteric and gene-based testing grew 17% for the quarter and by 11% for the full year. He said that Vitamin D testing volume had increased by 12% and that SureSwab volume was up by 40%.

Quest Diagnostics has told analysts that it intends to achieve a $500 millon reduction in costs in the next few years. This is an ambitious goal for a company that, early in 2007, had similarly pledged to remove $500 million in costs over the subsequent 36 months.

To achieve this goal, Quest's CFO, Robert A. Hagman, explained that specific teams had been organized and were focused on "specimen acquisition, which includes all the costs associated with obtaining and transporting samples; client support, which includes billing and customer service; the labs themselves and all the costs associated with operating them; IT and customer connectivity costs; procurement and supply chain; and SG&A, both in the field and at corporate."

$500 Million In Cost Savings

Hagman explained that about 1/3 of the targeted savings of $500 million will come from client support, procurement and supply chain. "We plan to leverage technology to eliminate manual work, further standardize systems and processes, implement more self-service options for customers, and leverage Lean Six Sigma to further streamline activities," he stated. "In client support and billing, we plan to reduce manual work and customer call volume by enabling customers to do more online, including supplying insurance information, making payments, checking on the status of a bill, and obtaining test results.

"...In the area of procurement and supply chain, we will further consolidate suppliers, rationalize SKUs, standardize and optimize specs, and work more closely with our suppliers in sharing information and managing costs from design to manufacture to distribution," continued Hagman. "We plan to... unlock the savings associated with bulk buying and the administration associated with handling all these different choices."

Simplifying Processes

As much as 1/3 of the targeted savings at Quest Diagnostics are "...expected to come from SG&A, including information technology (IT)," Hagman stated. "We are flattening the organization structure and simplifying management processes, which will not only reduce costs but drive increased accountability.

"In the area of IT, we will place greater emphasis on connectivity solutions which don't require computer hardware," he said. Over time, this will dramatically reduce the cost of serving the tens of thousands of pieces of equipment we have in the field. In addition, connectivity installations will be done quicker and at lower costs."

On the subject of physician adoption of Quest Diagnostics' IT solutions, Mohapatra told analysts that up to 200,000 physicians and clinicians currently use the company's Care360 system for lab test orders and lab test results. "Our Care360 electronic health record (EHR) is now utilized by 4,400 physicians and has enabled them to receive payments for meaningful use," added Mohapatra. "Last week, we announced a plan to help physicians nationwide adopt EHRs through our Care360 EHR grant program." On Quest's website, it states that,

Patient Visits to Office-Based Physicians Rose Slightly during the Fourth Quarter of 2011

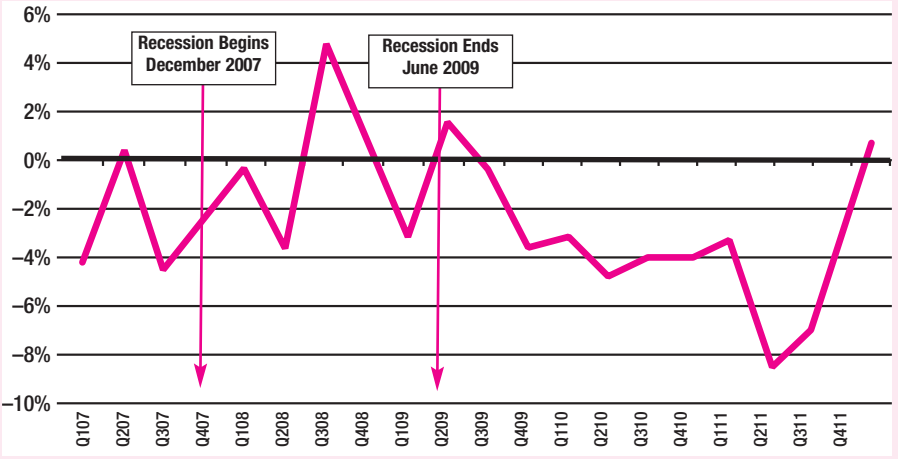
THE GRAPH BELOW SHOWS THE PERCENT CHANGE each quarter in the number of patient visits to physician offices from quarter one 2007 through quarter four 2011, as reported by **IMS Health**. The recession did not start until December 2007, yet a sustained trend of quarterly declines in patient visits to physician offices began as early as quarter one 2007.

Some experts connect the trend of declining office visits over this five-year period to both the recession (more unemployed individuals who don't have health insurance) and the higher deductibles and co-pays employees must pay as employers shift some of the increased cost of health benefits onto their employees. During 2010, in particular, financial analysts believed the ongoing quarterly declines in the number of patient visits to physician offices was a factor in the lackluster financial performance of the national laboratory companies. The start point and end point of the last recession is marked.

One notable observation is that, in only two quarters over the past five years did patient visits to physician offices increase in that quarter, compared to one year earlier. In fact, in each of the 10 quarters since the end of the recession, patient visits declined or remained flat, when compared to the same quarter in the previous year.

Physician Office Visit Trends

(Q1 2007–Q4 2011: Source: IMS Health)



in selected states, the company will pay for up to 85% of the cost of the Care360 EMR and pharmacy management solution.

In the area of anatomic pathology (AP), Quest Diagnostics continued to see an erosion of revenue. In 2011, the decline in AP revenue was 5%, which was an improvement from 2010, when AP revenue decreased by 10%. "...that's a piece of our business that we expect will continue to be under pressure from insourcing," stated Hagman during the conference call.

Quest Diagnostics wants to leverage its low prices, particularly when compared to how hospital laboratory outreach programs bill for testing services. In response to an analyst's question about what steps Quest Diagnostics is taking to

help managed care plans drive lab testing to the cheaper labs in payer networks, Mohapatra replied that, along with discussions with payers "...we're talking to the employers, and the whole objective is... to meet their goals, they [the payers] have to persuade the doctors to send the testing to our network and to avoid the high-cost providers [like hospital labs]."

In its conference call with financial analysts, LabCorp specifically called attention to projects to improve lab operations and change the patient experience. For example, during the call, LabCorp CEO David King talked about how his company is automating certain patient service functions.

In specimen collection, the centerpiece of this strategy seems to be LabCorp's "Touch AccuDraw" system. "The system is now deployed in more than 1,100 sites across the country and is processing over 1 million accessions per month," observed King. "We continue to enhance the system that allows our phlebotomists, a critical link in our sample flow, to improve accuracy, workflow and processing time to enhance the patient experience in our patient service centers (PSC)."

Automation in PSCs

LabCorp wants to deploy this solution across all its patient service centers and even into physician offices where it maintains its own phlebotomists. The company plans to implement voice-activated appointment scheduling for patients, so those patients "who do not want to use computers can schedule an appointment without a live operator," noted King. "We will explore collecting demographics in advance of patient encounters so that we can further expedite the blood-drawing process and improve the patient experience."

Vitamin D testing and histology/anatomic pathology trends at LabCorp are similar to those at Quest Diagnostics. Without mentioning a specific number, LabCorp CFO Brad Hayes told analysts that, when measured by volume, there is a "flattening of Vitamin D and also flattening in our histology business."

LabCorp's cost-cutting energies are directed toward workflow redesign in lab operations and more use of automation. King specifically mentioned efforts involving "lab automation, patient service center automation, and improvements in throughput of instrumentation."

How To Deliver More Growth

Both national laboratory companies must deal with more challenges to deliver the level of growth that is sought by investors. The truth of that conclusion is reflected in the topics emphasized by the executives at each lab firm, particularly the emphasis given to internal cost-cutting initiatives.

Clearly both companies are spending substantial capital to increase their use of information technology, particularly in ways that improve patient service levels. In this way, the service bar in the competitive marketplace will be raised.

Process improvement and workflow redesign via the use of Lean, Six Sigma, and similar management methods are getting more attention within both national lab firms. There will be increased deployment of laboratory automation in ways that support Lean work flow.

But what may turn out to be the most interesting development for the national laboratory market is that—if Quest Diagnostics and LabCorp have reached a plateau in their ability to increase market share—then continued use of deeply-discounted lab test prices will begin to work against them. After all, how can any lab make money when it sells tests at prices that are less than its fully-loaded cost? *(See related story on pages 3-6.)*

Thus, with options for increasing specimen volume ever more limited, will both lab companies quietly begin to raise prices on their existing business? After all, that is one proven way to increase net profits in ways that please shareholders. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

One of the nation's more clever business models for hospital laboratories is co-tenancy. It is a proven way that lab administrators can reduce the cost of inpatient testing. It is for this reason that the **Michigan Co-Tenancy Laboratory** in Ann Arbor, Michigan continues to grow. It announced that, during the past quarter, three hospital systems executed co-tenancy agreements and became active participants. They are **MaineHealth-Nor-Dx** of Scarborough, Maine; **Sparrow Health System** of Lansing Michigan; and, **St. Bernard's Medical Center** of Jonesboro, Arkansas.

ADD TO: *Co-Tenancy*

It was in 1997 when several health systems in Michigan joined with **Warde Medical Laboratories** to form the not-for-profit Michigan Co-Tenancy Laboratory. Growth has been steady. Currently there are 28 not-for-profit health systems in nine states that participate in this shared laboratory ownership model. The arrangement gives participating hospitals and health systems a way to lower the overall cost of inpatient lab testing while enjoying access to a broad menu of reference and esoteric tests.

HALFPENNY RAISES $2.25 MILLION

Things must be hot in the "lab hub" and LIS-to-EMR interface market. For the second time in the past 24 months, **Halfpenny Technologies, Inc.**, of Blue Bell, Pennsylvania, has boosted its capital base. On February 22, Halfpenny disclosed it had raised $2.25 million, which closes out its Series A round of $6.6 million. It was in October, 2010 that the company raised $2.25 million in capital from venture capital companies. One area of growth for Halfpenny is working with health insurers to give them more capability to collect and handle laboratory test data.

TRANSITIONS

• **ARUP Laboratories, Inc.**, of Salt Lake City, Utah, announced that Khosrow Shotorbani was selected to head up its newly-created "Business Innovations Division." Shotorbani is currently the Senior Vice President and Director of Sales at ARUP.

• Jack Shaw will retire from **Joint Venture Hospital Laboratories** (JVHL) of Detroit, Michigan, effective March 31. As Executive Director of JVHL, Shaw oversaw the founding of this regional laboratory network in 1992. He will also step down as President of **MedNet Services**.

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*Preview–**Ken Blick, Ph.D.,** Univ. of Oklahoma:*

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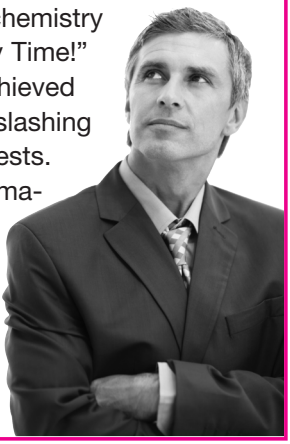

It was an ambitious goal in the high volume chemistry lab: Achieve "Every Test—Just in Time, Every Time!" Yet the lab staff rose to the challenge and achieved Six Sigma performance for one assay, while slashing turnaround times across the entire menu of tests. Learn how the laboratory team blended automation, middleware, and Lean to continuously improve the performance of the laboratory in ways that earned the respect of ED staff and other clinicians within the health system.

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