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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

More IVD Consolidation as Danaher Buys Beckman

TODAY IT WAS ANNOUNCED that **Danaher Corporation** would acquire **Beckman Coulter, Inc.**, in a transaction valued at $5.8 billion. The news was not a surprise, since word had leaked out last December that Beckman's board of director had engaged **Goldman Sachs** to advise it about a potential sale.

For lab administrators and pathologists, the significance of this acquisition is that consolidation within the *in vitro* diagnostics (IVD) industry continues. Beckman Coulter was itself created from a series of acquisitions.

It was 1997 when Beckman purchased **Coulter Corporation**. *(See TDR, October 6, 1997.)* And it was in early 2009 when Beckman acquired the clinical diagnostics business of **Olympus Corporation**. *(See TDR, March 16, 2009.)*

For its part, Danaher has used acquisitions to build up its Medical Technologies Segment. This business division will report sales of about $4 billion for 2010 and includes revenue from three business areas: life sciences, diagnostics, and dental. Danaher lumps life sciences and diagnostics together.

At Beckman Coulter, clinical diagnostics represent 88% of the company's total revenue and life sciences makes up the balance. Beckman will report sales of about $3.6 billion for 2010.

Thus, when Danaher combines the Beckman businesses with its existing life sciences and diagnostics companies, it will be one of the world's largest manufacturers of products for both the life sciences and clinical diagnostics markets. Over the past several years, Danaher has shown a keen appetite to acquire firms with a strong technology base in molecular and genetic testing. On that count, Beckman Coulter should be a good fit.

Danaher's acquisition of Beckman Coulter, like Beckman's acquisition of the clinical diagnostics of Olympus in early 2009, demonstrates how quickly consolidation can change the competitive marketplace for laboratory analyzers and laboratory automation equipment. This has consequences for clinical laboratory managers and pathologists who want continuity in the IVD companies that manufacture and support the analytical systems used in their laboratories.

Consolidation in the IVD sector is likely to continue. Already some financial analysts predict that the Obamacare 2.3% medical device tax that takes effect in 2013 will pressure medical device and IVD manufacturers to cut costs. Implementation of that tax may trigger more IVD acquisitions. TDR

$241 Million May Settle Quest Medi-Cal Claims

Lab company suspended billing Medi-Cal, but continues to provide lab testing to patients

CEO SUMMARY: There's movement in the negotiations between California state officials and Quest Diagnostics Incorporated over allegations that discounted lab test prices violated state law. In January, Quest disclosed that it had an "understanding" with California regulators and the amount of $241 million is part of the terms. It was also revealed that Medi-Cal payments to Quest Diagnostics are suspended through March 1, 2011, even as the lab company continues to provide testing.

IT MAY TAKE AS MUCH AS $241 MILLION for **Quest Diagnostics Incorporated** to eventually resolve allegations that it overcharged California's Medi-Cal program for laboratory testing services and violated the California False Claims Act.

This figure was disclosed by Quest Diagnostics in a press release about its fourth quarter 2010 earnings report, issued on January 25, 2011. It wrote that in "the fourth quarter of 2010, the Company reached an understanding, which was highly conditioned, to settle [both California] matters pursuant to which the Company would pay $241 million."

Further, Quest Diagnostics wrote "Conditions included, but were not limited to, reaching an agreement regarding the manner in which the Company's future billings would be treated by the Department." In this same statement Quest Diagnostics vowed to "vigorously defend itself" if a settlement could not ultimately be reached.

Another disclosure that caught the attention of laboratory executives and pathologists was Quest Diagnostic's acknowledgement that the Medi-Cal program had suspended payments to the company, although Quest Diagnostics was continuing to provide testing services to Medi-Cal patients.

Quest Diagnostics wrote that "While the Company believes it is in compliance in all material respects with California requirements applicable to billing for clinical laboratory testing, the Company entered into an interim agreement under which it has agreed to temporarily suspend billing Medi-Cal for a period of up to six

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months through March 1, 2011, during which it continues to provide services."

The language used by Quest Diagnostics to describe its negotiations with California state officials is being carefully parsed by medical laboratory owners and their attorneys in the Golden State. That's because many laboratory companies are themselves the target of either or both of two ongoing enforcement actions by state regulators.

Discounted Pricing Practices

At the center of this disruptive legal dispute is California Code of Regulations (CCR), Title 22, section 51501(a). It states, in part, "Notwithstanding any other provisions of these regulations, no provider shall charge for any service or any article more than would have been charged for the same service or article to other purchasers of comparable services or articles under comparable circumstances..."

This is a "best price" statute. According to the state's interpretation, when a provider gives another provider a service at a price below Medi-Cal, California's Medicaid program, then 51501(a) requires that the provider should also extend that same low price to Medi-Cal. This statute has been on the books since the birth of the federal Medicaid program some 40 years ago.

However, over these same decades, it has been a common practice for clinical laboratory companies to extend deeply-discounted laboratory test prices to certain providers, even as they submitted laboratory test claims to the Medi-Cal program at the higher prices of the Medi-Cal lab test fee schedule.

Two Enforcement Actions

Now state officials are vigorously pursuing enforcement of 51501(a) in two ways. One enforcement action is the *qui tam* lawsuit. Plaintiffs are the State of California *ex rel.* Hunter Laboratories, LLC, and Chris Riedel, an individual. The defendants are at least seven laboratory companies. The lawsuit was filed in 2005. The California Attorney General joined this lawsuit and unsealed it in early 2009. *(See TDR, April 6, 2009.)*

The second enforcement action involves the California **Department of Health Care Services** (DHCS). In a series of actions in 2010, the state agency put selected laboratory companies on notice that it was enforcing its interpretation of section 51501(a). *(See TDR, December 27, 2010.)*

Lots of lawyers are now billing for lots of hours in California as state officials and medical laboratory owners square off over these allegations that deeply-discounted laboratory test prices violate state statutes.

Thus, the public information provided by Quest Diagnostics on January 25 offers useful details about how California state officials may intend to settle these allegations—not just with Quest Diagnostics—but with the other laboratory companies caught up in one or both of these enforcement actions.

"As Go Quest and LabCorp"

Lab industry executives know that: "as go **Quest Diagnostics Incorporated** and **Laboratory Corporation of America**, so goes the rest of the industry." What makes this true is that both lab companies have billions of dollars of revenue and armies of top corporate lawyers to press their legal case.

So if the high-powered legal teams of each of the two blood brothers end up settling for significant sums—and agreeing to comply with the California DHCS's interpretation of 51501(a)—then it is highly probable that other clinical laboratories operating in the state will be expected to abide by these same terms.

With each passing month, it becomes likely that the deeply-discounted laboratory test prices that were so common in California over the past 20 years will not continue into the future. How that alters the Golden State's intensely-competitive market remains to be seen. TDR

Expect Changes in How Calif. Labs Set Test Prices

With hundreds of millions of dollars at stake, California healthcare regulators are acting tough

CEO SUMMARY: What a difference two years makes. Back in April, 2009, when then-Attorney General Jerry Brown joined the whistleblower lawsuit alleging that seven or more California lab companies had violated state law on pricing provider services, the popular wisdom among lab executives was that this case was going nowhere. Now, in recent weeks, the nation's largest lab has disclosed an "understanding" with California officials that includes a settlement of as much as $241 million.

FOR MORE THAN 20 YEARS, deeply-discounted laboratory test prices have been an oft-used sales strategy for many lab companies in California. Now it appears that two state government enforcement actions may soon change how laboratories set prices for lab tests in the Golden State.

As this happens, several things are likely to occur. First, state officials may end up collecting several hundred million dollars from the different laboratory companies that are targeted by these two state enforcement actions. One of the nation's two largest lab companies issued a press release last month and disclosed that its negotiations with California healthcare regulators involve a possible payment to the state of $241 million.

Second, last year's settlement agreement between **Westcliff Medical Laboratories, Inc.**, and the California **Department of Health Care Services** (DHCS) should be considered a template for the terms that DHCS officials probably want as they negotiate settlement agreements with other laboratories. In this agreement, there was a requirement for Westcliff to regularly audit the prices it charged its clients compared to the prices it charged Medi-Cal.

If it identified instances where a client got a lower price for an assay than what the lab billed Medi-Cal for the same assay, Westcliff was to refund the difference back to Medi-Cal. This policy is consistent with DHCS's interpretation of the state law on pricing.

Two Schools Of Thought

Third, there is uncertainty as to how laboratories may decide to price lab tests in California once the state's Attorney General and DHCS officials have completed these enforcement actions. There are two schools of thought on this matter.

Some lab executives point out that, if the DHCS's interpretation of the state statute on pricing prevails, then most laboratory companies would raise all laboratory test prices to at least equal the Medi-Cal lab test fee schedule. Were this to happen, profits at these laboratories would increase.

On the other hand, there are also those who speculate that larger lab companies

may choose to continue offering deeply-discounted prices to certain customers and only for specific tests. These lab companies would then charge Medi-Cal the same low prices for those assays as their most favored clients in order to comply with DHCS's interpretation of state laws.

Lab executives who describe this scenario also make the point that public lab companies have generally been willing to use marginal cost pricing to capture market share. So why would these lab companies enforce price discipline on themselves now if they believed that offering deeply-discounted pricing to selected customers while giving those same low prices to Medi-Cal could help them win and keep extra market share?

Media Have Not Done Stories

So far, the media in California have paid little attention to the wider public policy implications of the whistleblower lawsuit and related enforcement actions by DHCS. There has been no media investigation into how and why the DHCS's enforcement actions might cause patients, physicians, and health plans to pay significantly more money for laboratory tests. That would be an unfavorable public policy outcome.

Another interesting issue involves how DHCS has suspended Medi-Cal payments to **Quest Diagnostics Incorporated**, under a six-month agreement that expires on March 1, 2011. At the same time, Quest Diagnostics continues to provide testing to Medi-Cal patients.

This summer, Medi-Cal suspended payments to as many as 30 laboratory companies for what it alleged to be violations of state law on pricing for lab services. However, within weeks it restored payments to these lab firms while settlement talks continued. *(See TDR, December 17, 2010.)*

Thus, what are the policy issues that caused state officials to handle Quest Diagnostics differently than the other laboratory companies which received suspension letters from DHCS, but later had their Medi-Cal payments restored? The state is not saying.

DHCS Also Audited LabCorp

On this point, **Laboratory Corporation of America** has publicly stated that it responded to a DHCS audit during third quarter. Like Quest, LabCorp "believes that it has properly charged the Medi-Cal program under all applicable laws and regulations." It has similarly denied the accusations.

Quest has announced that DHCS suspended payments to it for Medi-Cal lab test claims. On the surface, it appears that DHCS is treating Quest Diagnostics differently, compared to other laboratory companies operating in California.

Some lab executives in the Golden State have suggested that DHCS's approach toward the nation's largest laboratory company may be a sign that the "too big to fail" principle is operative. They observe that DHCS cannot afford the negative publicity were its enforcement actions against laboratory companies in the state to disrupt healthcare services.

Further, because Quest Diagnostics holds such a dominant market share in California, laboratory executives believe that state healthcare regulators want to settle that case in order to establish a precedent. That settlement agreement would then establish the parameters that DHCS would use in its negotiations with other clinical laboratories.

Court Dates Grow Near

With the nation's largest laboratory company disclosing an "understanding" with the nation's most populous state and mentioning a number of $241 million, it would appear that California's healthcare regulators are holding strong cards at this moment. Also helping the state is the fact that trial dates for the two blood brothers are set for later in 2011. At trial, if they did not prevail, these lab firms would face the risk of treble damages and up to $10,000 for every one of the millions of Medi-Cal claims involved in each case. TDR

Lab Briefs

SPECTRUM-CARILION NOW WILL BE CALLED SOLSTAS LAB PARTNERS

IT IS THE NEXT STEP IN THE INTEGRATION of **Spectrum Laboratory Network** and **Carilion Laboratories**. Effective February 1, 2011, their combined businesses will use the name **Solstas Lab Partners**.

Both Spectrum Lab Network, located in Greensboro, North Carolina, and Carilion, based in Roanoke, Virginia, were acquired by **Welsh, Carson, Anderson, & Stowe** in early 2010. The operations of the two laboratory companies were merged in March, 2010.

DNA DIRECT GAINS MORE CLIENTS FOR PAYER PRE-AUTHORIZATION OF MOLECULAR TESTS

FOUR MORE HEALTH INSURANCE PLANS recently signed contracts with **DNA Direct, Inc.**, to use its Policy & Benefits Support Program for molecular and genetic tests. Payer pre-authorization for these tests is an important lab industry trend.

On January 31, 2011, DNA Direct announced that two regional health plans would use its pre-authorization service. The plans are **Qualchoice of Arkansas, Inc.**, and New York-based **Capital District Physicians Health Plan**.

Two other health insurers, **AultCare** (Ohio) and **Bluegrass Family Health** (Kentucky), will use a more limited form of DNA Direct's Policy & Benefits Support Program. DNA Direct will provide case review services and use its genetic experts "to provide health plans with on demand coverage guidance."

"Due to the increasing number of genetic tests coming on the market, there is confusion among physicians, patients, and payers about which tests are clinically appropriate," stated Ryan Phelan, Founder and President of DNA Direct. "We are working with innovative health plans that want to get ahead of the curve and implement an effective strategy to provide the necessary clinical guidance and support for providers and patients."

The company says that molecular and genetic tests are available for more than 2,000 diseases. It anticipates that about 300 new genetic tests will arrive in the clinical marketplace each year.

DNA Direct is regularly adding new genetic tests to its online portal that includes both clinical information about specific molecular test and coverage decision support tools. The online resouce is intended to educate payers about individual tests and support coverage decisions by the payers.

Currently, DNA Direct says that its program "enables payers to determine coverage for more than 800 molecular diagnostic and genetic tests and provides real time access to the DNA Direct team of clinical experts for clinical guidance on more than 2,000 tests available today."

PATHOLOGY, INC. ANNOUNCES ITS FIRST CLINICAL LAB ACQUISITION

ON JANUARY 24, 2011, **Pathology Inc.**, of Torrance, California, announced its acquisition of **Central Coast Clinical Laboratories** (CCCL), which is located in Templeton, California, near San Luis Obispo.

CCCL was founded in 2003. It provides clinical laboratory testing services to office-based physicians around San Luis Obispo and other communities along California's central coast.

This is the first laboratory acquisition for Pathology, Inc., which now describes itself as "the West's premier woman's health laboratory." Pathology, Inc., is an

anatomic pathology laboratory. Thus, its purchase of CCCL gives it access to a broad menu of clinical laboratory tests.

CCCL is the second independent clinical laboratory company in California to decide to sell itself in recent weeks. It was December 31, 2010, when **Physicians Automated Laboratory, Inc.**, (PAL) of Bakersfield, California, sold itself to **Sonic Healthcare, Ltd.** That acquisition was Sonic's first purchase of a laboratory company in California.

SLONE PARTNERS SELECTED TO RECRUIT NEW CEO FOR PAML

ONE OF THE NATION'S PREMIER CLINICAL LABORATORY CEO POSITIONS becomes available at the end of 2011. That's when Thomas O. Tiffany, Ph.D., DABCC, FACB, retires after 24 years at the helm of **Pathology Associates Medical Laboratories** (PAML), in Spokane, Washington.

Handling the executive search is **Slone Partners**, based in Miami Beach, Florida. Slone Partners is performing the search on behalf of PAML's owners, **Providence Health & Services** (PHS) and **Catholic Health Initiatives** (CHI).

"LAB" CAN SNIFF OUT COLON CANCER AT AN EARLY STAGE

IMAGINE A DOG THAT CAN IDENTIFY EARLY STAGE COLON CANCER approaching the sensitivity of a colonoscopy. Yes, the lab in question is a Labrador retriever!

Bloomberg reported that a research team in Japan trained the Labrador retriever to sniff out colon cancer. Next, the dog was presented with breath and stool samples of 300 patients before they received colonoscopies.

Of this number, 48 individuals had been recently diagnosised with colon cancer. The remainder of the patients representing individuals who were healthy, who were cancer survivors, or who were diagnosed with another colorectal illness.

With his associates, Dr. Hideto Sonoda of the Department of Surgery and Science Graduate School of Medicine at **Kyushu University**, Japan, determined that the Labrador could detect colon cancer with 95% accuracy when compared against a colonoscopy. The dog's accuracy increased to 98% when smelling the stool samples.

Another finding was that the Laborador could differentiate between polyps and malignancies, as well as detecting early stage cancer. Colonoscopies have limited effectiveness in these areas.

"This study shows that a specific cancer smell does indeed exist," wrote the researchers in *Gut*, a medical journal. "These odor materials may become effective tools in screening."

FIRST BABY BOOMERS TURN 65 YEARS OLD IN 2011

BACK IN 1946, MILLIONS OF BABY BOOMER BABIES ARRIVED and immediately began to change American society. Now, in 2011, those same baby boomers are becoming senior citizens and will launch a new cycle of change in the United States.

This is all happening because, as of January 1, 2011, the oldest baby boomers celebrated their 65th birthdays and became eligible for Social Security and Medicare. Enrollment in both programs will zoom upward this year.

Lab administrators and pathologists would do well to take note of the statistics. According the **American Association of Retired Persons** (AARP), every eight seconds, another 65 people will become eligible for Medicare. That's a total of 7,000 new enrollees every day.

What makes 2011 and later years different from 2010 and the past decade is that the number of new Social Security and Medicare beneficiaries will increase annually by a factor of 50%. When that larger number compounds over multiple years, it projects that the spending on Medicare, as a percentage of GDP, will jump from its current 3.4% to 6.4% in 20 years. TDR

Lab Informatics

Sunquest's LIS Product First To Earn Certification from CCHIT

IF THERE WAS A RACE TO BE FIRST TO OFFER a laboratory information system (LIS) product that is certified to be compliant as an (EHR) electronic health record module by CCHIT, then **Sunquest Information Systems, Inc.**, has attained that achievement.

On January 21, 2011, the **Certification Commission for Health Information Technology** (CCHIT), an ONC-ATCB, issued a certificate for Sunquest Laboratory version 6.4.2. The 2011/2012 criteria support the Stage 1 meaningful use measures required to qualify eligible providers and hospitals for funding under the American Recovery and Reinvestment Act (ARRA).

Under ARRA, hospitals investing in an EHR system may qualify for an initial $2 million incentive payment, with additional incentives payable based upon Medicare and Medicaid discharge rates. Physicians may qualify for more than $44,000 in incentive payments.

Meeting "Meaningful Use"

"For 2011/2012, the meaningful use criteria include mandatory items that providers must meet," stated Kelly A. Feist, Sunquest's Vice President, Marketing. "There is also a list of 10 items or functions, of which five must be demonstrated for providers to quality for the ARRA incentives.

"For laboratories, the particularly relevant function is criteria 170.306 (g), Reportable Laboratory Results," she continued. "This defines as the capability for the EHR Module to electronically record, retrieve, and submit laboratory test results containing LOINC codes in HL7 v2.5.1 format to public health and other agencies.

"Chief information officers at sites using our software tell our market researchers that, in the near term, they will concentrate on meeting the Phase I criteria," Feist explained. "However, they also want to meet the anticipated LOINC requirements in Phases II and III of meaningful use.

Future Use of LOINC

"Phase II and III criteria are anticipated to include the use of LOINC when communicating results received from reference labs. "We anticipate that hospitals and health systems will recognize the benefit of enabling the LIS to act as the enterprise LOINC Hub," noted Feist. "This will eliminate the need to maintain test dictionaries, test menus, and LOINC translations in more than one place. It also gives hospitals and laboratories a way to add new molecular and genetic tests to the menu and to use reference labs for their business needs."

The certificate issued by CCHIT to the Sunquest Laboratory version 6.4.2 covers compliance with 10 specific items that make up the 2011/2012 Phase One criteria. Included are: Incorporate Lab Results; Reportable Lab Results; Integrity; and two criteria for encryption.

Sunquest's action to gain certification for its LIS product is a reminder to pathologists and lab administrators that it is important for their laboratory to actively participate in their enterprise's strategy for meeting Phase I meaningful use criteria. TDR

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MuirLab Innovates to Improve Outcomes, Slash Costs

Putting Centrifuges Into Courier Cars For Mobile Processing

CEO SUMMARY: To improve the quality of lab services it provides to more than 300 skilled nursing facilities (SNF) while reducing costs, MuirLab of Concord, California, has created a "mobile specimen processing" solution. It operates a fleet of courier cars with centrifuges and refrigerated storage. Now specimens transported by these cars arrive at the core lab already labeled and processed so they can go directly onto the automated line. This is just one part of an effort to advance patient care by integrating wireless informatics solutions with mobile processing.

TO TRANSFORM THE PERFORMANCE AND PRODUCTIVITY of its laboratory couriers, **MuirLab** of Concord, California, has gone high tech. It operates its courier cars as mobile accessioning units, so that when specimens reach the laboratory, they immediately go onto the automated line for testing!

"This accomplishes two things," observed Michael Tarwater, Executive Director at MuirLab. "First, mobile processing protects specimen integrity during transport. That leads to a higher-quality lab test result that improves patient care.

"Second, it reduces the overall cost of specimen collection, delivery, and specimen prep," he continued. "These cost savings underpin our ability to serve less profitable segments of the laboratory testing marketplace, such as skilled nursing facilities (SNF) and nursing homes."

These innovations have paid big dividends. "The improvement in specimen integrity during transport has been significant," declared Tarwater. "MuirLab decreased recollects by 48% from 2007 to 2010, even as total requisitions serviced increased by 45% during this same time."

In many ways, it's a "brave new world" for MuirLab's couriers and phlebotomists. Their daily routine involves use of Lean workflow and wireless real-time integrated informatics as they drive courier cars equipped with centrifuges and refrigerated storage.

THE DARK REPORT believes MuirLab is unique in the United States in its innovative approach. By adding the functions of specimen accessioning and specimen preparation to the collection and transport of specimens before they are delivered to the laboratory, MuirLab has demonstrated another way that clinical laboratories can improve quality while eliminating unnecessary costs.

In fact, it was the need to develop a cost-effective way to serve 300 SNF and nursing home clients that originally motivated MuirLab to apply Lean methods and technology to the specimen collection, transport, and pre-analytical functions.

"It is phlebotomists who drive to these client facilities," stated Tarwater. "They already do double duty, since they collect the specimen, then hop into a car and drive it to the laboratory or to one of our courier/logistics hubs.

"Now we support their workflow in an intelligent manner," he continued. "At a client's site, the phlebotomist first uses wireless laptops to verify patient information before collecting specimens. A wireless printer produces labels at the patient's side. This system also, via wireless, registers the patient requisitions with our laboratory information system (LIS).

"Each courier car is equipped with centrifuges and refrigeration units," said Tarwater. "Specimen processing and preparation can start at the client's location. The refrigeration units in each courier car are monitored wirelessly so that staff at the core lab will know instantly if a sample is compromised.

Laboratory Outreach Growth

"MuirLab has a fast-growing lab outreach program," he said. "Each day, we process about 3,800 requisitions, representing 8,400 tests. About half our outreach volume originates at about 300 SNFs. These facilities are located as much as 100 miles from our central lab.

"It is no mystery to most pathologists and clinical lab managers that skilled nursing facility clients are notoriously low-margin operations for the lab that services them," explained Tarwater. "That is why we continously do everything possible to drive more efficiency into this part of our laboratory operation."

MuirLab's outreach program has 300 full-time staff members. This includes 35 phlebotomists and 12 staff members in the information technology department. On any given day, MuirLab visits about one third of its SNF clients and collects around 1,800 samples.

"From my standpoint, the overall story in many labs is about how we face continuing

pressure of lower reimbursement per test, particularly from Medicare," declared Tarwater. "Where Medicare goes, the other payers tend to also go.

"That continued pressure on reimbursement means that the laboratory has to figure out ways to get more efficient," he noted. "SNFs have a high proportion of Medicare patients. It is expensive for the laboratory to send out phlebotomists to the nursing homes to collect the specimens and bring them back to the laboratory. Thus, shrinking reimbursement adds to the lab's challenge of breaking even while meeting the service needs of nursing home clients."

Starting Point Of The Story

This is the starting point in MuirLab's story of the multi-tasking phlebotomists and centrifuge-equipped courier cars. There was an immediate need to significantly reduce the costs associated with serving its 300 nursing home clients—along with the urgency to do it quickly, since reimbursement associated with nursing home testing is generally below the cost to service that client.

"We didn't immediately attack the costs of servicing SNF clients," recalled Tarwater. "In recent years, MuirLab was focused on designing, building, and bringing into operation a state-of-the-art automated central laboratory.

"Our priority was getting automation in place in the core lab, then fine-tuning it in support of all our testing activities," he said. "Once we did that, it was time to address ways to improve the pre-analytical and the post-analytical steps in the process.

Reduce Unnecessary Costs

"What quickly hit our radar screen was the need to address the costs involved in specimen collection, specimen transport, and specimen preparation involving samples from nursing home clients," added Tarwater. "These are steps in the pre-analytical stage. Improvements in workflow and individual work processes upstream of the automated laboratory would also directly benefit our analytical stage performance."

Application of Lean and work flow redesign methods helped the MuirLab team identify opportunities to improve the quality of work processes, reduce rates of errors and defects, and eliminate sources of waste and unnecessary cost. In the nursing home segment of the business, this can mean the difference between losing money and breaking even for the laboratory that provides testing to SNFs.

"In developing our new workflow solutions in specimen collection, specimen transport, and specimen preparation, we actively looked for ways that technology could support increased efficiency, accuracy, and quality," said Tarwater. "That is a key to understanding why these new approaches have been successful in sustained use."

MuirLab's secret sauce in its innovative solution are the courier cars used by the phlebotomists who visit each SNF to collect specimens. "We operate these courier cars as mobile pre-processing units," stated Tarwater. "The goal is simple. When the courier car arrives at our core laboratory, all the specimens it delivers can go directly onto our automation line. Every courier car used by a phlebotomist has centrifuges and a refrigerated unit."

Wireless Support

"Each phlebotomist goes out with a laptop, a wireless label printer, and a wireless internet connection," he said. "At the patient's side, the phlebotomist can look up the orders and print the labels as they collect the samples. This technology supports on-demand orders (non-standing or recurring orders.)

"Before leaving for the next location, the phlebotomist will put the samples in the centrifuge and spin them," noted Tarwater. "Once prepped, the specimens are then refrigerated.

"Collectively, these steps save about five to six minutes per specimen" Tarwater

Why Servicing 300 Skilled Nursing Facilities Is a Tough Financial and Service Challenge

"PATHOLOGISTS KNOW THAT THERE are very tight margins in servicing skilled nursing facilities (SNF) and nursing homes," noted Michael Tarwater, Executive Director of Muir Labs in Concord, California.

"Anything we can do to identify and cut wasted time and eliminate non-value-added processes, the more efficient our laboratory will be," added Tarwater. "To help us pare down the expense of providing laboratory testing services to SNFs, we wanted to rethink the pre-analytical phase. That includes specimen collection at the time when the phlebotomist visits the client SNF to obtain specimens; specimen transport; and the processing and preparation of the specimens.

"This is how we recognized the value of having a courier vehicle run parallel tasks instead of doing the serial tasks—or simply sitting idle while a phlebotomist collects the specimen," he said. "Multi-tasking lets you take full advantage of that vehicle.

"This insight came as a direct result of the guiding management principle here at MuirLab, which is to continuously improve what we do every day and every hour," he observed. "It is important to understand that what we've accomplished with our multi-tasking phlebotomy and courier workflow is rooted in several core management values.

Reengineering Workflow

"Reengineering is at the heart of how we view activities in our laboratory," explained Tarwater. "Staff constantly looks for opportunities to improve processes and to eliminate non-value-added steps.

"Every clinical laboratory needs highly efficient processes that are scalable and repeatable. MuirLab is no exception," he declared. "Scalable and repeatable processes allow you to predict your outcomes. In turn, that predictability is what drives the lab's ability to regularly improve quality."

If Tarwater sounds like he's well-schooled in Lean and process improvement, it's because two of his main responsibilities at MuirLab are laboratory information systems and quality management. Also, before coming into the laboratory testing business, he gained experience in other industries.

Extensive Experience

"In addition to my 13 years of clinical laboratory experience, I also have an extensive background in information technology (IT), transportation, and manufacturing distribution," he says. "So, I brought all those skills to this laboratory.

"I view our core laboratory as a factory and our product is information," he commented. "Our laboratory must render that information in multiple different formats while also ensuring the quality and integrity of that information.

"Like every medical laboratory, MuirLab takes data and turns it into information," continued Tarwater. "Our laboratory must accomplish this using repeatable and scalable methods even as it continues to improve the quality of the information that it produces.

"Anything we can do to save time, steps, and non-value-added processes, the more efficient we will be in the pre-analytical stage. So if we have a vehicle running parallel tasks instead of doing tasks serially or sitting there idle while a phlebotomist does the drawing, then we are taking full advantage of that vehicle."

added. "That is because, when they arrive at the lab, these specimens are ready to immediately be put on the automated line. They don't need to go through processing to check the order, print the label, and they don't have to be spun. Instead, they already have the barcode label from the wireless printer, were logged on via the wireless link at the client's site, and go directly to the analyzers."

California's hot summer climate played a role in designing solutions for specimen handling and specimen transport. "A significant part of our service region is the high desert of California, where the temperature can get over 100 degrees in the summer," he observed. "Also, some of our clients are located 100 miles away from our core laboratory. Maintaining specimen integrity with coolers and dry ice under these conditions is always a challenge.

"We did our first courier cars like this about four years ago," added Tarwater. "For us, combining centrifuges and refrigerated units in the courier cars immediately paid big dividends. Spinning and refrigerating the specimens before transport stabilizes them and helps prevent them from being compromised in the heat."

"Anytime a specimen is compromised, it means we would have to recollect that sample, and that could require at least another day," he stated. "With this new work flow, there has been measurable reduction in the number of compromised specimens. Each of these steps contributes to improved patient care."

Adding Costs, Cutting Staff

"Of course, we do have the cost of adding centrifuges and a refrigeration unit to our vehicles," he stated. "We spend about $3,900 per car on this retrofitting. Our fleet includes such Toyota models as the Prius, Corolla, and Yaris.

"In each car, the passenger seat is removed to allow the installation of a two-centrifuge sub-assembly made to our specifications," continued Tarwater. "Each centrifuge holds six to eight specimens and can run side by side in case one breaks down.

"The refrigeration unit goes in the backseat," he said. "This unit is about the size of a large camping cooler and has a built-in compressor. A battery pack is installed in the trunk to power all that equipment."

These courier cars have another feature. "We have sensors in the refrigerated units that relay the temperature back to our central laboratory wirelessly and continuously in each cooler in each car," added Tarwater. "That way we know if a specimen has been compromised."

Used For Other Purposes

On hot days, MuirLab may also use the specially-equipped courier cars when serving a lab or client located some distance away. "Since the temperature can often top 100 degrees in the summer, we'll use one of the cars with refrigeration to ensure that the specimens are stable," Tarwater stated. "This is a great help because we cover a lot of geography. The core lab is in Concord and we go over 70 miles to the north, 80 miles to the east, and 100 miles to the south.

"There are about 180 cars in our fleet and 35 cars are retrofitted with this equipment," added Tarwater. "Courier cars used to collect specimens from our patient service centers (PSC) do not have centrifuges because the PSC staff spins those samples on site.

"The additional cost of equipping 35 courier cars with these centrifuges and refrigeration units is more than offset by the resulting savings," he noted. "For example, we have reduced the work associated with processing specimens as they arrive in the lab. Further, we reduced the need to send staff out to recollect specimens if any are compromised.

"Like many labs, we track our vehicles with GPS (global positioning satellite) so that our dispatchers know where each vehicle is at any given point," Tarwater

observed. "It also helps us check their average speed and their top speed. Not only do we want safe drivers, but these cars do prominently display the name of our laboratory.

"Now that we have improved the pre-analytical processes that we use to service our SNFs and other clients, we are ready to go one step further this year," commented Tarwater. "Since the bulk of orders from SNFs are standing orders and don't change much from day to day, we are preparing to install an improved and robust application to handle these standing orders.

"This new application will allow us to pre-print by route all standing order labels and the companion draw sheet," he explained. "When phlebotomists start their route, they can pick up a packet of the scheduled work for that day. The labels will be sorted by route, and by facility and that information will be in our LIS. When the phlebotomist arrives at a client facility, he or she will only need to enter that day's on-demand orders on their laptops."

Process Improvement's Role

It is oft said that necessity is the mother of invention. Certainly the need for MuirLab to reduce the cost of servicing a money-losing group of clients was the motivation to develop these clever solutions.

However, an equally important part of this story is how Lean, process improvement, and similar quality management methods gave MuirLab team the tools needed to analyze existing workflow, and identify sources of waste. It gave them a roadmap for developing, testing, and implementing solutions that would have a high likelihood of success. This is important validation of workflow redesign methods.

The result is a highly innovative solution that is unique among clinical laboratories in the United States. MuirLab has developed the business model of the multi-tasking phlebotomist and the courier car as a mobile station for specimen preparation and specimen processing.

Economics Are Tough When Labs Serve SNFs

IT'S NO SECRET THAT SKILLED NURSING FACILITIES (SNFs) place intense service demands on clinical laboratories, while offering meager reimbursement. This means most laboratories lose money from their nursing home business.

In fact, it was during the mid-1990s when all the nation's biggest independent laboratory companies dropped nursing home clients, precisely because they were unprofitable to service. Into that vacuum stepped many hospital laboratories, often as a way to further the strategy of their parent hospitals or health systems to build strong clinical relationships with the SNFs in their community. The hospital benefits when the SNF refers it patients who need to be admitted for an inpatient stay.

For this reason, hospital administrators will absorb the operating losses incurred from the laboratory outreach testing services delivered to a client SNF, in exchange for access to the inpatient referrals from that SNF.

That is why the management team at MuirLab is working diligently to continuously develop and implement workflow solutions that reduce the cost to service a nursing home client, even as these same process improvement projects contribute to better quality, lower costs, and improved patient outcomes.

In doing this, MuirLab points the way forward for other hospital and health system laboratories that provide laboratory testing services to skilled nursing facilities. It is an innovation that, when deployed by other laboratories, can help them improve the lab testing services they deliver to SNFs while significantly reducing the costs associated with those clients. TDR

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—Joe Burns

Using Audits to Uncover Bad Data in the Lab

More lab managers are taking steps to verify the accuracy of data used to measure processes

CEO SUMMARY: Labs using Lean, Six Sigma, and similar quality management methods are now putting these tools to a new purpose. They are being employed to validate the accuracy of metrics designed to monitor and manage work processes directly related to turnaround times and customer satisfaction. In auditing how such data is collected, lab administrators are often surprised at the inaccuracy of the data sets collected and relied upon—often for years—to measure performance.

ACCURATE DATA IS THE CORNERSTONE of laboratory medicine. Accurate data is also fundamental to evaluating the performance of operational work processes in the clinical laboratory and pathology group.

In recent years, a small, but growing, number of laboratories have begun to question the accuracy of data used to measure the performance of individual work processes within their labs.

"Two things motivate these laboratories to question the precision of the data they collect as part of their ongoing quality assurance activities," stated Rodney Momcilovic, a consultant with the **ValuMetrix** division of **Ortho-Clinical Diagnostics**, a business unit of **Johnson & Johnson**.

Measuring Individual Steps

"First, as a laboratory organization adopts the quality management methods of Lean, Six Sigma, and process improvement, its staff learns new ways to measure individual steps in a work process," explained Momcilovic. "One consequence of these new skills is that staff begins to recognize flaws in how data is collected.

"The second reason is that the tools and methods used in Lean and continuous improvement give the laboratory's staff the capability to fix those flaws in data collection," he said. "Technology may also play a role in fixing the flaws in data collection, because middleware solutions make it easier for lab staff to capture more granular data in real time."

Momcilovic made these comments to a packed room at last November's *Lab Quality Confab*, conducted in San Antonio, Texas. His session was titled "Unlock Major Performance Gains by Managing Your Lab's Work Flow with Real-Time Performance Measures."

The keen interest of his audience in how to better utilize real-time data to guide performance improvement projects was itself a statement. It demonstrated how competitive forces in the laboratory marketplace are causing more lab administrators to look inward into their lab's operation to identify the sources of errors.

These lab managers know that eliminating errors and shortening turnaround times produces competitive advantage in the marketplace. As this happens their lab

is raising the bar in the market and other labs must step up their performance to maintain their competitive position.

"Essentially, these laboratories have decided to challenge the assumption that much of the data on work processes they have collected for years is accurate," observed Momcilovic. "Too often, their finding is that this is bad data—and it has been bad data for all the years they collected it."

Non-Clinical Data Accuracy

"At the heart of quality assurance in the laboratory is the regular audit of processes to be sure that the lab test results are accurate," he said. "But how often do lab administrators audit the non-clinical data that they use in quality improvement efforts? Not often enough! That is why lab managers may unknowingly be using bad data to make critical decisions."

"A great illustration of this are the time stamps in the LIS that laboratories routinely use to help measure their turnaround-times," continued Momcilovic. "Time stamps are only as reliable as the process for creating them.

"It's the old cliché of 'garbage in, garbage out'," he added. "If the time stamp is entered incorrectly or at the wrong step in the process, you end up with a completely irrelevant measure.

"Here's an example of a flawed time stamp process," stated Momcilovic. "In a consulting project with a lab client, their monthly reports showed that patients waited an average of 11 minutes to have blood drawn, which they thought was very good.

"However, the lab was receiving negative patient satisfaction scores due to long wait times," he said. "Customer feedback motivated lab administrators to further reduce wait times to improve patient statisfaction—despite the fact that the reports based on the time stamps said the lab's wait times were good.

"To determine what was actually happening, I took my stopwatch to the outpatient waiting area," he recalled. "We measured how long patients actually waited from the time they approached the registration desk until the time they were called for their blood draw.

"The findings confirmed that patient dissatisfaction was justified," Momcilovic revealed. "Patients waited much longer than the time stamp data suggested. Many waited as long as 30 minutes before they were called by the phlebotomist.

"When the lab team reviewed how the time stamp data was collected, the bad data factor was quickly recognized," he noted. "Clerks entered a time stamp when patients registered. That started the wait time measure.

"To mark the end of the patient wait time, the next time stamp was to be created when the order entry clerks *completed* the paperwork and moved it to the ready-to-draw basket," he explained. "However, clerks often created the stamp when they *started* the paperwork.

"This generated bad data because the time stamp was only measuring the time from registration to the time the paperwork was moved to the order entry basket," he added. "This was only a small portion of the patient's actual wait time.

Simple Fix To The Problem

"The fix from bad data to good data was simple," Momcilovic said. "The second time stamp was now collected at the point when the phlebotomist picked up the order and actually called the patient in for the blood draw."

Armed with verified data, lab administrators had accurate metrics for improvement. "In this case, the bottleneck was the ordering process," he explained. "Basic workflow changes were made to the two-person team doing the order entry. Average wait times—now measured by accurate time stamps—fell under eight minutes. Patient satisfaction scores rose.

"Data collection errors like this are common in the lab," Momcilovic said,

"Such bad data make it tough for lab administrators to reliably identify where the problems exist in their labs' work processes."

Momcilovic offered another common way that labs unwittingly collect bad data on work processes. "Assume that big batches of samples arrive in the lab at one time," he said. "Maybe one accessioner decides to speed up the data entry process by giving all the samples the same drawn and received times.

"Here is an example of how this hides customer dissatisfaction," he offered. "Take a sample drawn at 7 a.m., but entered by the accessioner as drawn at 7:44 and received at 7:45. If the result is ready at 8:30, the TAT, according to the computer, is 45 minutes. But for the physician waiting for results, it's a TAT of 90 minutes, double what your data shows.

"If you use that bad data to benchmark your service, it hides the defects in your lab's service," Momcilovic observed. "In the meantime, the physicians are unhappy and your lab team cannot understand why."

"Such a simple habit makes it impossible for management to use the time stamp data to know how long it takes the samples to get to the lab," he continued. "It takes just one out of 10 accessioners taking this shortcut to seriously skew the time stamp data in the LIS."

Important To Audit

Momcilovic recommends that laboratories regularly audit the process of data collection to improve its accuracy. "Your lab's quality control (QC) team regularly audits the quality of analytical data. Why shouldn't the data sets used to determine the performance of work processes also be audited?" he asked.

"The best audits physically watch how things are done," he continued. "Lab directors are always surprised at what we find when we audit their processes. The process may be a good process. But should the people who perform that process take shortcuts, it could render the collected data unreliable."

While variations in data may seem trivial, they can seriously skew statistical data, especially when the data is averaged over a month or over a year. "Seconds count, minutes matter and hours add up," he says.

Auditing can also help lab managers accurately identify the source of bottlenecks. "One client was preparing to purchase a new piece of equipment because doctors told him that it was taking too long to get results from the analyzer," Momcilovic said. "When we audited the processes, he discovered that the analyzer was providing rapid results, but the results often sat waiting for verification by a med tech. If he hadn't audited the process, he might have spent $250,000 and gotten no improvement.

Implementing A Solution

"Instead, the lab administrator changed the process to ensure a regular time interval for frequent results review and release until autoverification could be incorporated," he said. "This delivered a big improvement in speed at no cost."

While physical auditing takes time, it is often the only way to verify if the data is accurate. "If you use that data to create budgets and determine staffing levels, to guide capital expenditures, or to alter processes in your laboratory, you need to know that the data is creditable and that it truly measures what you are intending to measure," says Momcilovic.

"If you do the audit and it turns out the data is reliable, you haven't wasted your time. If the data is ever questioned, you'll have first-hand knowledge of its credibility," he added. TDR

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

In Nigeria, the kidnap of a professor of pathology at the **University of Uyno** last month caused work stoppages by academic union members in protest of the government's failure to protect medical faculty from the recent rash of kidnappings. Pathologist Dr. Memfin Ekpo was abducted by gunmen during a church service on January 16. His family was contacted by the kidnappers and asked to pay a ransom of 50 million naira (about $329,000). This demand was later reduced to 20 million naira. As of press time, Dr. Ekpo had not been freed by the kidnappers.

MORE ON: *Kidnap*

Pathologist Memfin Ekpo's abduction was the sixth of a faculty member working at the University of Uyo, which is the largest university in Nigeria. Faculty and workers at the university are upset at the failure of local and national security forces and police to find the kidnappers, as well as to prevent further such kidnappings. Their work stoppages are intended to pressure law enforcement authorities to both find and free Dr. Ekpo and to prevent further kidnappings of faculty members. It is not known if pathology associations in other countries have provided any support or have made public comments in response to Dr. Ekpo's kidnapping and continuing captivity.

GE TO BUILD DIGITAL PATHOLOGY CENTER IN TORONTO

In tandem, **General Electric Co.,** and **Omnyx, LLC**, its digital pathology joint venture, announced that they will build a Pathology Imaging Center of Excellence in Toronto, Canada. The center is intended to further develop digital pathology solutions and act as a resource in the adoption of digital pathology worldwide.

TRANSITIONS

•**Sysmex America**, of Mundelein, Illinois, announced three new executive promotions. Robert Degnan will serve as Executive Vice President, Commercial Operations. Ralph Taylor will serve as Executive Vice President, Marketing, Business Development, and Medical/Scientific Affairs. Andrew (Andy) Hay is now Vice President of Sales.

•**Pacific Diagnostic Laboratories, LLC**, of Santa Barbara, California, hired Wayne Wecksler, Ph.D., to be its new General Manager. Wecksler previously was General Manager for the Van Nuys laboratory of **Quest Diagnostics Incorporated**.

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Clinical Laboratory and Pathology News/Trends

DARK DAILY UPDATE

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

...the **Veteran Administration** (VA) invested $4 billion in health info technology (IT) and reaped $7 billion in savings over the past decade. It is evidence that integrated health IT produces savings.

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That's all the insider intelligence for this report. Look for the next briefing on Monday, February 28, 2011.