



From the Desk of R. Lewis Dark...

THE **RD** DARK REPORT

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

R. Lewis Dark:

Securing Your Lab’s Success as Healthcare Reforms.....Page 2

Hospital Labs Feel More Pressure
From Payers to Lower Prices.....Page 3

Payer Trend in New Hampshire
Is to Engage Lab PatientsPage 5

Critical Access Hospitals
Losing Laboratory Test WorkPage 8

Ohio Lab Offers Lessons Learned
From CAP 15189 AccreditationPage 11

Lab Briefs: LifeLabs, Gamma-Dynacare,
Sonic Healthcare, Brigham & Women's Hospital,
Massachusetts General HospitalPage 15

Exome Sequencing Next
“Big Thing” for Diagnosis.....Page 16

Intelligence: Late-Breaking Lab News.....Page 19

COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher



Securing Your Lab's Success as Healthcare Reforms

IT IS PROBABLY SAFE TO ASSUME THAT MOST OF YOU RECOGNIZE that the American healthcare system is about to undergo its most extensive transformation of the past 50 years. For better or for worse, we are about to see the end of medicine dominated by fee-for-service reimbursement and a fragmented delivery system.

What is predicted to take its place is a medical system in which clinical care is fully integrated and supported by an equally-integrated health informatics backbone. This has important strategic and operational consequences for both clinical laboratories and anatomic pathology groups.

As an ancillary service, the laboratory testing profession has been very good at serving independent provider organizations. Across healthcare today, probably no single clinical service is as good as laboratories at serving hundreds, thousands, and tens of thousands of physicians' offices, nursing homes, and other categories of health providers.

Since the mid-1980s, it has been clinical laboratory organizations which were consistently first to introduce enhanced information technology services. It is the lab industry that made it faster, easier, and more productive for providers to use advanced information technology to order laboratory tests, accept the lab test results, and access the laboratory test data of their patients.

Now we are about to see the widespread adoption of accountable care organizations (ACO), medical homes, and similar models of integrated care. Hospitals and health systems are buying up physician practices. Health insurers are also purchasing physician groups. Collectively, all of these unfolding trends portend big changes in how providers utilize clinical laboratory testing.

I predict that the clinical labs and pathology groups which enjoy the greatest success during this major reconfiguration of the American healthcare system will be those which are good at using information technology to multiply the value of the lab testing services they provide daily to physicians.

That should be no surprise. Along with innovations in health informatics, it has been the nation's medical labs that regularly introduce new diagnostic technologies that allow physicians to make faster, more accurate diagnoses, then select the best therapies. In my view, the successful lab organizations during this transformation of American healthcare will be those that leverage informatics and new diagnostic technology to deliver added value as providers undergo their own integration into ACOs, medical homes, and the like.

Hospital Labs Feel More Pressure to Lower Prices

➤ **Health insurers negotiate to reduce test prices from hospital/health system lab outreach programs**

➤➤ **CEO SUMMARY: It's a new trend and gathering momentum. At managed care contract renewal time, more hospitals and health systems report much stronger pressure from health insurers to accept deep cuts to laboratory test prices. At the same time, managed care companies are getting smarter at designing health benefits plans that motivate and/or incentivize patients to choose lower-cost network laboratory providers. Hospital laboratory outreach programs need a response to these developments.**

LIKE NEVER BEFORE, health insurers are putting strong pressure on hospitals to dramatically reduce the price of their outpatient and outreach laboratory tests.

Across, the nation, hospital lab administrators are telling THE DARK REPORT that—in current contract discussions—payers are clearly more aggressive about wanting substantial reductions in lab test prices. More to the point, payers now persistently demand that hospital and health system labs accept deep discounts to existing hospital lab test price schedules.

THE DARK REPORT has tracked this trend since early evidence surfaced about 18 months ago. In this issue, THE DARK REPORT provides the first analysis of this important development to be published for the laboratory testing industry.

One visible example of this trend is a health plan called “site of service” option. It was launched by **Anthem Blue Cross Blue Shield in New Hampshire** in January, 2010. It involves outpatient/outreach services for lab testing and ambulatory surgery.

As you will read on pages 5-7, patients who use Anthem’s three network lab companies have zero out-of-pocket expenses. Anthem describes the site of service option as giving patients “cost saving, value-based benefit options.”

However, since introduction of the site of service plan by Anthem, hospitals across New Hampshire—particularly rural and critical access hospitals—have watched their lab test volumes shrink. At the same time, patients are asking hospitals to collect their lab specimens, then send those speci-

THIS PRIVATE PUBLICATION contains restricted and confidential information subject to the TERMS OF USAGE on envelope seal, breakage of which signifies the reader's acceptance thereof.

THE DARK REPORT Intelligence Briefings for Laboratory CEOs, COOs, CFOs, and Pathologists are sent 17 times per year by The Dark Group, Inc., 21806 Briarcliff Drive, Spicewood, Texas, 78669, Voice 1.800.560.6363, Fax 512.264.0969. (ISSN 1097-2919.)

R. Lewis Dark, Founder & Publisher.

Robert L. Michel, Editor.

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).

NO PART of this Intelligence Document may be printed without written permission. Intelligence and information contained in this Report are carefully gathered from sources we believe to be reliable, but we cannot guarantee the accuracy of all information.

visit: www.darkreport.com • © The Dark Group, Inc. 2012 • All Rights Reserved

mens to one of Anthem's in-network laboratories for testing.

On pages 8-10, the CEO of a rural, critical access hospital in New Hampshire explains how Anthem's site of service insurance product is eating away at the financial and clinical capability of her institution. With her hospital laboratory receiving fewer specimens, it means a reduced in-house lab test menu, along with less revenue to support the hospital's entire clinical service offering.

► What The Evidence Indicates

The timing of this trend is not a coincidence. The fingerprints of the national lab companies can be found on much of the evidence that is available to the public.

Over the past decade, the two national laboratory companies have regularly lost market share to local hospital and health system outreach programs in community after community. There are many examples of well-run hospital laboratory outreach programs that have enjoyed impressive annual rates of growth in specimen volume and revenue.

Over these same years, both **Quest Diagnostics Incorporated** and **Laboratory Corporation of America** have been criticized by Wall Street analysts and investors for their inability to capture more market share of office-based physician laboratory test referrals.

To counter the cumulative competitive threat of hundreds of hospital and health system laboratory outreach programs, each of the two Blood Brothers has developed a similar strategy to leverage their one unquestionable competitive advantage over smaller lab testing organizations.

That advantage is the economies of scale that accrue to both national laboratory companies because of their high volumes of specimens and their huge regional testing facilities. The traditional way to leverage these economies of scale was to give major health insurance companies deeply-discounted prices for lab tests. Independent

lab companies and hospital lab outreach programs found it impossible to match these deeply-discounted lab test prices.

Thus, these same labs were excluded from the payer's lab networks. That left the two national labs as the primary network lab providers, from which they expected to leverage new physician clients and access the pull-through fee-for-service specimens needed to offset the losses expected from deeply-discounted contract prices for lab tests.

That strategy has not been fully successful. Substantial numbers of office-based physicians continued to prefer and use their local hospital outreach programs. Neither of the two national labs were able to consistently reduce the rate of leakage in ways that satisfied most managed care plans.

Physicians' role in this story is their resistance to efforts by managed care plans to steer patients to the lower-cost network labs. Managed care plans could only do so much to enforce physician adherence to the in-network labs providers and reduce leakage before angering the doctors.

In response to this situation, it appears that the new strategy of the two national laboratories is to educate and continually remind payers about the much higher prices charged by many hospital laboratory outreach programs.

It is reasonable to interpret the evidence and conclude that, if the two national labs could not shift leakage in their favor, they would begin a campaign to educate health insurers about the higher prices payers were paying for hospital lab outpatient and outreach tests. Then, health insurers would go to the negotiating table with these same hospitals and be more persistent in demanding that hospitals accept a lower contract price for outpatient/outreach lab tests.

For hospital labs, these developments now make it essential to know the accurate cost of lab testing. This information can then be used to better negotiate fair lab test prices when renewing managed care contracts.

Trend in New Hampshire Is to Engage Lab Patients

➤ **Insurer's 'site of service' cost-sharing option incentivizes patients to use lower cost providers**

➤➤ ***CEO SUMMARY: A health insurer's two-year-old effort to have patients choose low-cost laboratory testing options is causing patients to shift their lab work away from New Hampshire's hospitals and instead use Quest Diagnostics, LabCorp, and ConVerge (a commercial lab company). This new health insurance program offers a number of important lessons for pathologists and lab directors because it shows that, when hospital labs are willing to negotiate lower rates for lab services, they may be able to retain managed care contracts. If not, health plans are prepared to go elsewhere.***

IN NEW HAMPSHIRE, ONE MAJOR HEALTH INSURER is working diligently to lower the cost it must pay for clinical laboratory testing. The payer initiated these efforts in response to the needs of the employers who offer the payer's health plans to their employees.

Anthem Blue Cross Blue Shield in New Hampshire has developed a value-based benefits strategy for two clinical services: lab testing and ambulatory surgery. For pathologists and lab administrators, Anthem's implementation of this strategy for laboratory testing services is instructive as to why major health plans are more actively managing compliance with their lab testing networks.

➤ **Meeting Employers' Needs**

"Anthem's value-based benefits strategy is proving to be a big win for its employer customers, and the brokers who sell contracts for health plans to employers," stated Maria M. Proulx, Senior Legal Counsel for Anthem in New Hampshire.

Anthem BCBS in New Hampshire is owned by **Wellpoint, Inc.** One of the

nation's largest managed care organizations, Wellpoint serves 34.5 million medical members in 14 states.

For its New Hampshire members, Anthem has three primary laboratory companies in its network: **Quest Diagnostics Incorporated, Laboratory Corporation of America, and ConVerge Diagnostic Services**, of Peabody, Massachusetts.

This story began two years ago. "In December 2009, we instituted a program we call the 'site of service option,'" recalled Robert J. Noonan, Vice President, Provider Engagement and Contracting, for Anthem in New Hampshire. "One goal for this site of service program was to develop cost-sharing options for our members.

"When a member chooses a lower cost site for laboratory tests, that member can share in the savings," explained Noonan. "In fact, patients have zero out-of-pocket costs for laboratory tests if they go to Quest, LabCorp, or ConVerge.

"Further, we negotiated lower prices for laboratory tests with two of the state's 26 hospitals," he said. "Our members have

zero out-of-pocket costs when the clinical laboratory testing is performed by these two hospitals as well.”

Noonan explained that—when hospitals are willing to lower the cost of their laboratory services—they will be considered lower-cost, site of service locations.

“When we negotiated with those two hospitals, they saw that their rates were higher than the rates we pay to the independent labs and they didn’t want to lose access to Anthem’s members,” he explained. “We are having similar discussions with the other 24 hospitals, but so far, only two have agreed to lower their rates.

“Currently, then, should members want to get their lab testing performed at any of the other 24 hospitals in New Hampshire, they have a co-pay and must meet a deductible,” he added. “Patients can go to all hospitals in New Hampshire to have their specimens collected. But if the patient wants the zero-out-of-pocket option, as of this date, only the two hospitals in our network are considered lower-cost options.”

► Can Labs Add Value?

Anthem is looking to encourage laboratories in the state to innovate and add value. “Currently, as we look at medical laboratory testing, it is basically a commodity service,” observed Noonan. “It is not difficult to do a CBC, for example. That’s what Quest, LabCorp, and ConVerge do all day, every day. So, turnaround time, quality, and reporting back to the doctors’ offices for these labs is as good as it is anywhere.

“Before we introduced this site of service option, there was not much competition among the hospitals and there was a small number of free-standing labs in our state,” he continued. “The status quo was that hospital labs generally controlled their local markets. Hospitals were consolidating market share by acquiring physician practices. Each hospital would then strongly encourage its employed physicians to refer their patients to the hospital laboratories.

“Those market dynamics prompted us to introduce these value-based, cost-sharing benefit options,” stated Noonan. “It gives our members a financial incentive to seek clinical services—whether for a laboratory test or ambulatory surgery—from lower-cost providers. When they do, they share in the savings.”

► Difference In Lab Test Prices

Noonan said that the difference in the price of lab testing was often substantial. “I don’t have the exact numbers and it varies at each hospital, but it is common for a lab test to cost something like three times as much if it is performed by a hospital laboratory, rather than by Quest, LabCorp, or Converge,” he commented. “That is a big difference. It is one reason why we wanted to change the market dynamics so that there would be a motivation for labs to compete more intensely, and not just on lower price.”

Proulx added that Anthem members still have a choice when it comes to lab testing services. “It is important to note that some hospitals feel that we have built this narrow network in New Hampshire to exclude them,” she noted. “However, that has not been done. All of our members can get their lab testing at any hospital laboratory. It is their choice and the only issue is how much they are willing to pay out of their own pocket.

“Members who pay attention and educate themselves about the cost of care should be rewarded for making smart choices,” she emphasized. “By implementing the site of service program as a cost-sharing option, members have a choice. If a member doesn’t want a lower cost, he or she can go where it is most convenient.”

► Premiums Cut by 5% to 15%

Proulx said that members, employers, and insurance brokers have reacted positively to the site of service option. “They like this program because the premiums for our health plans that offer the site of service option can be 5% to 15% lower than the pre-

mium for a plan that does not include the site of service cost-sharing option,” she said.

“The brokers are very happy to sell health plans with the site of service option during the slow economy,” Proulx noted. “It’s been a time when employers consider it highly important to save every dime.”

Noonan added, for example, that the cost of insurance for a family of four is over \$15,000 in New Hampshire. That is among the highest premium rates in the nation, he said.

From Anthem’s perspective, there is also more competition among labs in the network to add value to the patient experience. “At the 2009 launch of our site of service option, our three contract labs—ConVerge, LabCorp, and Quest Diagnostics— had only 13 patient service centers (PSCs) in New Hampshire. Since then, these lab companies added 17 PSCs in two years. That brings the number of PSCs today to 30 across the state,” explained Noonan.

“We see this as a demonstration of our partnership with these three lab companies,” he stated. “Those 17 new PSCs represent a lot of bricks and mortar.”

➤ **Mobile Phlebotomy Van**

Another innovation that has appeared since the site of service option was introduced is a mobile phlebotomy van. This raises the competitive bar on patient service among laboratories in the Granite State.

“There is value to patients in a phlebotomy service that comes to their homes to collect lab test specimens,” emphasized Noonan. “In the northern part of the state, which is rural, members in plans with our site of service option need convenient access for blood draws and collection of lab test specimens.

“To serve Anthem members in the three northernmost counties, Quest Diagnostics introduced what it calls ‘Exam One,’ a mobile phlebotomy unit,” concluded Noonan. “This mobile phlebotomy unit will come to your home in Carroll, Coos, and Grafton counties.”

NH Lawmakers Voted Law for Patient Choice

LEGISLATION IN NEW HAMPSHIRE was recently passed specifically to allow more patient choice. The law was a response to the trend of hospitals buying and operating physician practices.

According to Maria M. Proulx, Senior Legal Counsel for Anthem Blue Cross Blue Shield of New Hampshire, this law played an important role in reshaping the market for healthcare in the state. “About two years ago, the New Hampshire legislature passed the freedom of choice provision,” she stated.

“This provision requires health insurers to put language in their contracts with physicians that says patients can seek healthcare services wherever they want,” said Proulx. “In other words, providers—such as office-based physicians—cannot insist that patients go to the hospitals that employ those physicians.

“The intent of this provision was to allow patients to regain the freedom of choice that they lost when hospitals bought physician groups, then required the physicians to send their patients to the hospitals’ ancillary services, including the clinical laboratory,” she continued. “That law makes it possible for Anthem’s site of service members to go wherever they want for their healthcare, including for their lab work.”

In New Hampshire today, hospitals own approximately 75% of the primary care physicians practicing in the state, she added.

THE DARK REPORT observes that health insurance companies nationwide are narrowing their provider networks and steering their members to low-cost laboratory service providers. Clinical laboratories that are willing to reduce their prices to be competitive with those of the national lab companies may retain more health plan business than those laboratories that refuse to lower their rates.

TDR

Contact Chris Dugan at 603-695-7202 or chris.dugan@anthem.com.

Critical Access Hospitals Losing Lab Test Work

► Rural hospitals across New Hampshire say less laboratory test volume may affect services

►► **CEO SUMMARY:** *One consequence of a new “site of service” health plan instituted by Anthem Blue Cross and Blue Shield in New Hampshire is that community hospitals—particularly in rural areas—are being asked by patients to collect blood and lab specimens, then send them off to Anthem’s network laboratories. One New Hampshire hospital CEO explains how the site-of-service rules are reducing the clinical capabilities of hospitals in some towns. This dispute is about the higher cost of hospital lab tests versus the discounted prices from independent labs.*

IT WAS ON JANUARY 1, 2010, when some hospitals in New Hampshire began to feel the effects of new rules by some private health insurance plans designed to steer members away from hospital labs and toward the payers’ network laboratory companies.

For example, **Anthem Blue Cross and Blue Shield in New Hampshire** introduced what it calls a new “site of service” benefit option for laboratory testing and ambulatory surgery. (See pages 3-7.) When members in this plan use any of the three Anthem network laboratories—**Quest Diagnostics Incorporated, Laboratory Corporation of America, and ConVerge Diagnostic Services, LLC**—they pay zero out-of-pocket costs.

Should the patient in the site-of-service plan use a non-network hospital laboratory, then a copay is required and deductible requirements must be met. Patients can still use hospital labs but they would pay more to do so, Anthem said.

A number of hospitals in the Granite State are affected by these developments,

particularly in rural areas. Michelle McEwen, FACHE, President and CEO of **Speare Memorial Hospital** in Plymouth, New Hampshire, said Speare has seen a spike in the number of patients who request that the hospital collect their blood and other laboratory specimens, but then direct the hospital to send those specimens to the independent lab companies in Anthem’s network for testing.

► Patients Steered Away

“We have seen an increase in the number of patients requesting us to draw their blood and send those lab samples to one of the approved labs,” McEwen said in an email to THE DARK REPORT. “This recent increase is due to the fact that this is the only benefit plan that Anthem offers to its small employer groups and many of our local employers renewed their health insurance benefits on January 1. It is still too early to tell what the full impact of this new benefit option will be. Not only does this plan direct lab patients away from hospitals, it does the same with ambulatory surgery patients.”

“Hospitals may choose to draw specimens if they want to provide this service to their community, and then send these out to an approved network lab for testing and results,” she said. “Reimbursement for doing so is very low and the hospital may incur additional costs to establish the courier services necessary to get the specimens to the appropriate lab.

“The larger issue is on the impact of patient care,” she added. “The hospital is the middle man in this process. We draw the lab specimen and send it out. When patients and physicians are looking for results and turn to the hospital, we can’t help. We are not in the loop to know that the lab received the specimens, or to receive results when that lab testing is done.

“The healthcare industry is moving toward increased integration and coordination of care for purposes of decreasing overall healthcare costs and improving quality,” noted McEwen. “This benefit plan does just the opposite. This product virtually forces patients to seek care outside of their local community, due to the financial penalties involved, and further fragments their care.”

Under Anthem’s site-of-service benefit option, patients pay no out-of-pocket costs when they choose a lower-cost clinical laboratory or ambulatory surgery center that is part of Anthem’s provider network.

➤ High-Volume Carve Out

The 25-bed Speare Memorial is a critical access hospital in the central part of the state between the lakes region and the White Mountain National Forest.

“There are many troubling points with this health insurance product,” McEwen wrote. “As a provider, it is disturbing to negotiate a contract with a large national organization such as Anthem for our full book of services, only to have them subsequently carve out high-volume services and send them elsewhere.

“The discount our institution negotiated with Anthem was based upon the

Anthem’s Website Explains \$0 Out-of-Pocket Benefit

ON ITS WEBSITE, ANTHEM Blue Cross and Blue Shield in New Hampshire said its “site of service” benefit option lets members pay zero out of pocket.

“By using labs found on Anthem’s Provider Finder, which include all independent labs in New Hampshire and some hospital labs, you will not have a copay for your lab services,” Anthem said.

“You have the choice to use any lab you’d like, however, if you choose a lab not found on Provider Finder, you may be subject to a higher cost share,” Anthem said, adding that independent labs provide the same type and quality of service as hospital outpatient labs.

“If you use one of the labs located on Anthem’s Provider Finder, you pay \$0 for services. Whether you need a blood, urine, or strep test, nothing comes out of your pocket. That means no deductible or coinsurance,” Anthem said.

expectation of obtaining a certain volume level, although they will not include these terms in their agreement,” she continued. “Once the deal was sealed, they made arrangements to send the volume elsewhere and still obtain the benefit of the volume discount.

“The funds generated by performing these lab tests are used to support the cost of providing laboratory services to all patients 24/7, including stat labs for emergency patients and inpatients,” McEwen explained. “These funds also help support other services in the hospital where losses are typically incurred, such as the emergency room and obstetric programs.

“While Anthem’s new product is pulling the lucrative outpatient services—such as lab and ambulatory surgery—away from hospitals, they still expect us to provide important urgent, emergency, and inpatient services to their patients

without the revenues needed to do so,” she added.

“Anthem was invited to meet with the **New Hampshire Critical Access Hospitals** to address our concerns with this product offering,” continued McEwen. “We clearly outlined our concerns with regard to the impact this product will have on the sustainability of small rural hospitals and specifically our ability to meet their members’ emergency and inpatient care needs. Anthem did not share our concerns.

“Therefore, they have not offered any alternatives, concessions, or understanding of the issue,” she added. “Collectively we have also approached the New Hampshire Department of Insurance for guidance, but state officials don’t seem to be aware of the product or its impact on access to care in rural areas.

►►►►

“Collectively we [rural hospitals] have also approached the New Hampshire Department of Insurance for guidance, but state officials don’t seem to be aware of the product or its impact on access to care in rural areas.”

“Anthem indicated that this was a business decision,” McEwen said. “They were simply responding to employer requests for lower premiums while maintaining their profitability.”

It is significant that the CEO of Speare Memorial Hospital wanted to speak out about the range of negative consequences that have surfaced after the “point-of-service” health insurance product was introduced by Anthem Blue Cross and Blue Shield in New Hampshire. As McEwen points out, small hospitals must carefully orchestrate the range of clinical

services they provide in order to operate in a financially-sustainable manner.

New Hampshire has 13 critical access hospitals, of which Speare Memorial Hospital is one. Each of these hospitals recognizes a fundamental economic fact about clinical laboratories: an adequate volume of specimens is required in order to support a broad menu of in-house testing at an affordable cost.

► **Two Benefits For Hospitals**

This is why losing access to the outreach and outpatient laboratory testing specimens can directly affect inpatient services at the rural hospital. Those additional volumes of outpatient and outreach lab specimens add the additional volume necessary for the hospital lab to set up and run those tests in-house. This has two benefits for the lab and its parent hospital.

First, it means the rural hospital lab can offer faster turnaround times for these lab tests to inpatients. That is a significant clinical benefit and contributes to better healthcare outcomes and a lower cost-per-healthcare encounter.

Second, access to additional lab specimens from outpatient and outreach settings increases the total volume of specimens flowing through the laboratory. In turn, this generates a lower average cost-per-test for the hospital, including inpatient testing.

Thus, McEwen is correct when she says that the loss of access to outpatient and outreach lab testing specimens does affect the mix of clinical services her hospital can offer. It also undermines the financial sustainability of her institution, since the revenue generated across all clinical services—including laboratory testing—is used to support the institution’s full range of clinical services it offers to physicians and patients in its rural community.

TDR

—Joseph Burns

Contact Michelle McEwen at info@speare-hospital.com.

Ohio Lab Offers Lessons Learned from CAP 15189

► **Mercy Med Center's lab wanted to stand out from other competing labs in Greater Canton**

►► **CEO SUMMARY:** *For a lab looking to continually improve lab operations, becoming accredited to either ISO 15189 or CAP 15189 is an ideal challenge. After hearing from other lab directors about the benefits of becoming accredited to CAP 15189, the staff at Mercy Medical Center in Canton, Ohio, believed that accreditation to this standard would allow them to move to the 'next level' in quality and patient care. Implementation of the quality management system (QMS) as part of the accreditation process has given staff new ways to improve quality across the laboratory.*

AS THE COMPETITIVE BAR FOR SERVICE and quality moves ever higher, some hospital lab directors are implementing a quality management system (QMS) to position their laboratory organizations as high-service providers.

It was recognition of the need to stay in front of their competitors in the Greater Canton, Ohio, region that motivated the staff at the **Mercy Medical Center** to implement the QMS of CAP 15189 last year. For both the laboratory and the staff, this decision has produced important benefits.

► **Mercy Lab's QMS Journey**

This QMS journey began in 2008. That's when members of Mercy's laboratory attended the THE DARK REPORT'S *Lab Quality Confab* program. This meeting features presentations by labs and pathology groups using Lean, Six Sigma, and process improvement methods in innovative ways. During *Lab Quality Confab*, the Mercy lab staff members heard about outcomes that early adopters of QMS programs were having.

"We constantly look for ways to improve operations, patient safety, and efficiencies," explained Mary Ann Burich-Boccia, MBA, MT (ASCP), SBB. She is Administrative Director, Department of Pathology and Laboratory Medicine at Mercy Medical Center. "After attending the conference and hearing from other lab administrators about the outcomes of these early adopters of CAP 15189, we believed that our lab's accreditation would move us to the 'next level.'

"In addition, we recognized the importance of looking at the laboratory as one unit and not as a number of different sections," noted Burich-Boccia. "We wanted to develop a system that enabled us to be more disciplined in practicing continual process improvement. We also wanted to implement steps that would help us prevent problems."

Mercy Medical Center is part of the **Sisters of Charity Health System**. This 476-bed hospital serves patients in five counties in Northeast Ohio. In addition to the core lab at the medical center, Mercy provides lab services at Mercy Health

Centers in Carroll, Plain, and Tuscarawas counties, and in the towns of Jackson, Lake, Louisville, and North Canton. It also runs **Mercy Laboratory Services** in Harrisburg and Little Flower. With a full-time staff of 141, including nine managers and a four-person pathology group, the lab did 1.6 million billable tests in 2011.

“Mercy Medical Center is known for having achieved a number of firsts in the region,” observed Burich-Boccia. “We recognized that our accreditation to 15189 would be recognized as another ‘first.’”

“Being an early adopter allows us to market ourselves as being first to earn accreditation to CAP 15189 in our region,” she added. “At this time, we believe we are also the only laboratory in our market area that is accredited to CAP 15189.”

► **Widely Known Accreditation**

“In the manufacturing community, ISO accreditation is widely recognized—much more so than other accreditations,” noted Burich-Boccia. “Our lab’s accreditation to 15189 sends a strong message about our commitment to having a QMS.”

“Within the laboratory community in our region, even though CAP 15189 is not the same as ISO 15189, it is an accreditation that other laboratorians recognize,” she continued. “They know it demonstrates our lab’s continuing commitment to quality patient care and service.”

“These are benefits that are distinct from the business advantages that adoption of the QMS is delivering to our laboratory,” stated Burich-Boccia. “We understand that, within our laboratory, every improvement to a process and every gain in efficiency while also reducing rework directly contributes to improvements in patient care and patient satisfaction. When physicians and patients understand this about our laboratory, we believe it encourages them to choose Mercy.”

“Of course, one direct economic benefit is our increased ability to lower our

costs as a result of having standardized processes that reduce variances,” she said. “This results in lower overall costs.”

Upon their return from the 2008 *Lab Quality Confab*, the Mercy lab team first had to convince health system administrators that earning accreditation to CAP 15189 and implementing a quality management system would truly deliver all of these benefits—both to the laboratory and its parent health system.

► **Confidence In The Strategy**

“The experiences of other lab directors at the confab gave us confidence that we could persuade the hospital administrators to agree to let us pursue CAP accreditation,” Burich-Boccia said. “We did our homework so that meetings with administration went well.”

“First, we explained the process of obtaining accreditation to the requirements of CAP 15189, along with the benefits that would follow,” she noted. “We emphasized that such accreditation is a public demonstration of our lab’s commitment to delivering quality patient care. We called attention to the fact that, once again, this would be one more opportunity for the laboratory to be recognized as a first-mover in the Greater Canton region.”

“Of course, the hospital administrators wanted to know how long it would take, what resources were required, and what the cost would be,” said Burich-Boccia. “In fact, the hospital’s chief operating officer requested these specifics on the program.”

► **Estimated Implementation Time**

“The only cost was the fee CAP charges facilities for accreditation,” she explained. “We estimated the time would be eight months. In reality, it took 18 months for our lab to earn accreditation to CAP 15189.”

“We did not incur other direct costs because we used staff time to get the job done,” commented Burich-Boccia. “It was not necessary to hire anyone nor incur overtime.”

“We did not purchase any software programs for document control because we used what resources we had in the lab,” she said. “We did purchase books and some appropriate online courses.”

Once it had gained approval by administration, the Mercy lab team took steps to keep administrators informed about the progress being made toward accreditation to CAP 15189. They also wanted to make administrators aware of the specific improvements that could be identified, along with the patient care and cost benefits that could be measured.

“We decided to advise the COO about our progress by inviting him to our regular laboratory meetings,” Burrich-Boccia explained. “We also involved him each time we gave a summation to the CAP 15189 surveyors.

“We regularly discussed the goals we had established for this project with the hospital administrators,” she noted. “We explained that we wanted a more robust QMS that crossed all functional areas of the laboratory. It was equally important to gain buy-in and the participation of all lab personnel.

► Lab Planned Next Steps

“When we had the approvals to begin the process of getting accredited, I asked Gayle Brown, MT(ASCP)SH, Lab Quality Systems Coordinator, to head up the project,” Burrich-Boccia said. “By taking the lead, Gayle kept us all on track. She began working on the accreditation project at about the beginning of 2009 and worked throughout that year to put everything in place. She drove us to succeed.”

By November 2009, the lab was ready to submit its application to CAP. “We had a desk assessment in January 2010,” stated Brown. “At that point we thought we were getting close to meeting all the accreditation criteria.”

That mindset changed when the first gap assessment was conducted. “It was March 2010 when the gap assessment

List of 15189-Accredited Laboratories Is Growing

WHEN A LABORATORY DECIDES TO PURSUE accreditation to ISO 15189 or CAP 15189, it still must meet the requirements of the federal Clinical Laboratory Improvement Act (CLIA). Here is a list of laboratory organizations which have met CAP 15189 accreditation requirements.

- Advanced Diagnostic Laboratories at National Jewish Health, *Denver, CO*
- Avera McKennan Hospital & University Health Center Main Laboratory, *Sioux Falls, SD*
- Blanchard Valley Hospital Laboratory, *Findlay, OH*
- Esoterix Genetic Laboratories, *Monrovia, CA*
- Esoterix Genetic Laboratories, *Phoenix, AZ*
- Laboratory Corporation of America, *Tampa, FL*
- Laboratory Corporation of America-Center For Molecular Biology and Pathology, *Research Triangle Park, NC*
- Mercy Medical Center-Pathology & Laboratory Medicine, *Canton, OH*
- National Medical Services, Inc. dba NMS Labs, *Willow Grove, PA*
- ProMedica Laboratories, *Toledo, OH*
- Quest Diagnostics Clinical Trials Laboratory, *Valencia, CA*
- Quintiles Laboratories Limited, *Marietta, GA*
- Quintiles Laboratories Limited, *Edinburgh, Scotland*
- TPMG (The Permanente Medical Group) Regional Laboratory Marina Way South, *Richmond, CA*
- TPMG Kaiser Regional Laboratories, *Berkeley, CA*
- TriCore Reference Laboratories, *Albuquerque, NM*

took place,” recalled Brown. “The important insight that came from this process was that we needed to involve the entire laboratory staff in this effort. Up to this point, only a few people had actively worked on this project.

“We were learning some of the secrets to being successful with accreditation to CAP 15189,” Brown said. “One of those secrets is that it is smart to engage the full commitment of everyone working within the laboratory.”

► **Selecting Internal Auditors**

Another essential step in preparing for accreditation is to develop and train internal auditors. “We identified internal auditors from our pool of laboratory medical technologists,” explained Burich-Boccia. “We selected several newly-graduated med techs for this role.

“It was our view that, as internal auditors, it would give these med techs a deeper understanding of the other side of laboratory operations,” she commented. “We wanted them to become familiar with the non-technical side, because then they would understand how the entire lab operates.”

Brown agreed. “Today, the staff has an entirely different perspective on what it takes to run the laboratory,” she observed. “It is significant that the entire staff of our laboratories have a new mindset about deficiencies. Let me explain why.

► **Root Cause Analysis**

“In the past, when we had a problem within the laboratory, we would just fix it and move on,” noted Brown. “But today, when there is a problem within one department of our lab, we conduct a root cause analysis. This allows us to fix the systemic cause of errors and/or unacceptable quality. Equally important, the findings of the root cause analysis allows us to determine if this same problem occurs in other departments. If it does, we can take corrective action, as appropriate.”

Looking back, Brown said there are some steps she would do differently. “When we started this process we didn’t know what to expect,” she recalled. “Also, there was a limited amount of information available, particularly about how to implement and sustain a quality management system in a clinical laboratory organization. If doing this today, we would take full advantage of all the educational material specific to CAP 15189 and to ISO 15189.

“Another thing we would do differently is to contact other lab facilities that have gone through the 15189 accreditation process to get their opinions on the experience,” continued Brown. “It would have better prepared us for the time required to prepare the laboratory for its first gap assessment, for example.”

Brown noted that input from other 15189-accredited laboratories would have been helpful in another way. “We would have understood that the implementation process—when done correctly—takes time and we should not be discouraged when our artificial timelines were not met,” she said.

► **Great Experience**

“Achieving accreditation to CAP 15189 has been a great experience for the management staff, in particular,” stated Brown. “They now ‘speak 15189’ and live it more so than ever. Each individual within the lab organization takes a different length of time to become aware of the process and incorporate it into daily actions. But as they ‘get it’, there is enthusiasm and motivation to apply these methods to improve quality and patient care in all aspects of what we do.”

THE DARK REPORT observes that the number of laboratories taking steps to implement a quality management system is increasing steadily. This is a trend which directly benefits both the lab testing profession and patients.

TDR

—By Joseph Burns

Contact Gayle Brown MT(ASCP)SH at 330-489-1224 or gayle.brown@cantonmercy.org.



Lab Briefs

►► LIFELABS QUEBEC TO BE ACQUIRED BY GAMMA-DYNACARE

LAST WEEK, IT WAS ANNOUNCED that **Gamma-Dynacare Medical Laboratories** had signed a definitive agreement with **LifeLabs Limited Partnership** to purchase **LifeLabs Quebec**. Both parties expect the transaction to close by April 28, 2012.

This laboratory acquisition is notable for at least three reasons. First, it involves Canada's two primary national laboratory companies, which are **LifeLabs, Inc.**, based in Toronto, Ontario; and **Gamma-Dynacare Medical Laboratories**, located in Brampton, Ontario.

Second, **Dynacare Laboratories**, is a division of **Laboratory Corporation of America**. **Dynacare** is a majority shareholder in **Gamma-Dynacare**. Thus, the willingness of **LabCorp** to approve the acquisition may indicate it continues to consider the lab testing market in Canada to be financially viable.

Third, this is the second lab recently acquired by **Gamma-Dynacare** in Quebec. It was last December when **Gamma-Dynacare** purchased **Warnex Medical Laboratory**, a lab company based in Laval, Quebec, and serving the Montreal and Quebec City metropolitan areas.

►► SONIC HEALTHCARE REPORTS GROWTH IN ITS U.S. LAB DIVISION

WITH SIZABLE MEDICAL LABORATORY TESTING BUSINESSES on three continents, **Sonic Healthcare, Ltd.**, offers a unique way to compare the lab test markets across different nations.

Sonic recently reported its earnings for the first six months of its current fiscal year, which ends on June 30, 2012. For the six-month period ending December 31, 2011, Sonic's revenue reached US\$1.8 bil-

lion. This represented growth of 11.8% over the same six months of the prior year.

Lab testing makes up 79% of the company's revenue, with radiology and medical centers comprising the balance, at 12% and 9%, respectively. For its clinical laboratory and pathology revenue, Sonic announced the following for constant currency revenue and percentage of total business (in U.S. dollars):

• Australia	\$513 million	30%
• United States	\$428 million	23%
• Europe	\$432 million	24%
• New Zealand	\$37 million	2%

Independent of laboratory acquisitions in the United States during 2011, Sonic disclosed that organic growth in the United States was 2%. By contrast, Sonic said that organic growth in its European laboratory division was 6% during the first six months of its current fiscal year.

Because of its laboratory acquisitions and sales development programs, Sonic Healthcare's lab testing business in the United States now generates in excess of \$850 million in annual revenue.

►► STUDY DETERMINES PHYSICIANS WHO USE DATA EXCHANGES ORDER FEWER LABORATORY TESTS

PHYSICIANS WHO USE A HEALTH INFORMATION EXCHANGE (HIE) and can access a patient's prior test results tend to order fewer laboratory tests than physicians who don't have HIE access. This is the finding of a recently-published study in the *Archives of Internal Medicine*.

The study was conducted using data from 117,606 outpatients who were seen at **Brigham and Women's Hospital** and **Massachusetts General Hospital** between January 1, 1999 and December 31, 2004. It was 2000 when the two hospitals established their HIE.

Exome Sequencing Next “Big Thing” for Diagnosis

► Exomes make up just 1.5% of human genome, yet this is where 85% of disease mutations exist

►► **CEO SUMMARY:** *For disease diagnostics, exome sequencing is not yet routine, but geneticists are getting close. Using this technology, researchers read those parts of the human genome where about 85% of disease-causing mutations reside. By looking only at the regions that encode proteins—the workhorse machinery of the cell—researchers identify disease causes much faster than with previous methods. The first diagnostic tests that utilize exome sequencing are starting to show up in the clinical market.*

ONE EMERGING FIELD in genetic testing involves exome sequencing. One by one, clinical applications based on exome sequencing are appearing.

Think of exomes as a potentially elegant shortcut to a diagnostic answer. The exome of the human genome is estimated to comprise 1.5% of the total genome. Researchers and *in vitro* diagnostic test (IVD) developers recognize that, by focusing on this 1.5% of the entire human genome, they can use exome sequencing to extract useful diagnostic information with the least cost and a fast time-to-answer.

► Exome Sequencing Potential

At the **Emory University School of Medicine** and **Sanford-Burnham Medical Research Institute** in Atlanta, researchers say exomes are like an executive summary scan of a person’s entire genome. In February, these researchers published a case report in the *American Journal of Human Genetics*, showing how they combined a simple blood test with an exome scan to diagnose a type of severe metabolic disease.

There is plenty of excitement about the potential for exome sequencing. Researchers at Emory and Sanford-Burnham note that use of this type of sequencing to diagnose disease is not yet routine, but geneticists are getting close.

“It is estimated that most disease-causing mutations (around 85%) are found within the regions of the genome that encode proteins, the workhorse machinery of the cell,” stated Emory and Sanford-Burnham in a press release about exome sequencing. “Whole-exome sequencing reads only the parts of the human genome that encode proteins, leaving the other 99% of the genome unread.”

One lab company that is a first-mover in its use of exome-based genetic tests in clinical diagnostics is **Ambry Genetics**, based in Aliso Viejo, California. Ambry says it is the first CAP-accredited and CLIA-certified lab to provide researchers, physicians, and pathologists with exome sequencing services. The company believes its Clinical Diagnostic Exome (CDE) test is the first to deliver clinical results.

For Cancer Diagnostics, Clinical Tests Based On Exome Sequencing Soon To Be on Lab Menus

WITHIN 10 YEARS, exome sequencing could become an important component for physicians diagnosing and treating cancer patients. That's the prediction of Jean Pierre Issa, M.D., an oncologist and researcher at **Temple University** in Philadelphia, Pennsylvania.

"Currently the gold standard for treating patients is sequencing one gene at a time using very accurate technology," Issa said. "People are comfortable with this. We have been using this technology to make diagnostic or treatment decisions for many years.

"The question is: do we replace that with exome sequencing? Or, do we still apply the gold standard and use exome sequencing as a discovery tool to increase our chances of finding something?" asked Issa.

"Some form of next-generation sequencing or exome sequencing will be essential for managing patients with cancer," he added. "Right now we are in the research phase and labs are struggling with whether this exome sequencing technology can be set up as a CLIA-approved test for managing patients or if it will remain as a research tool.

"For the degree of information clinicians get from exome sequencing, this technology has the potential to be a most cost effective technology," noted Issa. "But the question is: do we need that depth of information to make decisions when treating patients? Do we want the whole genome or do we use exome sequencing to get 20 or 30 genes, giving us something much more focused to specific diseases? That battle will play out over a few years.

"If the technology to do the whole genome is cheap enough then everyone will do that," he said. "But if it remains more expensive than doing 10 or 20 genes, then those technologies that do a more targeted approach will eventually win out.

"The next question is how reliable will this technology be," Issa added. "That's what I want to know for my patients. I may use exome sequencing as a first step and then use a different method to verify the results.

"That's our institutional thinking right now," he added. "I'm not convinced I can use exome sequencing with patients without validating the approach because there is no consensus yet on moving to the patient."

Elizabeth Chao, M.D., the Director of Translational Medicine for Ambry Genetics, agreed. "The accuracy of next-generation sequencing far exceeds that of traditional methodologies," she said.

"Next-generation sequencing is still new to clinical diagnostics and clinical exome sequencing even more so," she continued. "So today, we still confirm all positive exome results by Sanger sequencing (the gold standard) prior to reporting the results, thereby eliminating the need for the clinician to arrange or order any validation studies.

"With experience—both in our lab and in the field—the need for this additional validation step will no longer be necessary," concluded Chao. "That is the point when massive parallel sequencing will become the new standard."

Ambry says its CDE test can be used to identify genes for rare diseases or for complex cases when the diagnosis is unclear. The assay has also been used in pharmacogenomics research.

Earlier this year, Ambry used its CDE test to identify rare genetic conditions in four individuals whose health problems

had previously eluded diagnosis. "Right now, we apply the CDE test to cases where conventional genetic testing has failed," said Elizabeth Chao, M.D., Ambry's Director of Translational Medicine.

Ambry's Clinical Diagnostic Exome costs \$7,900. The company says that major national health insurers will often cover the

cost of this testing. Current turnaround time for a CDE test is 8 to 16 weeks.

“All of about 20,000 human genes are included as part of the test, with coverage for over 300,000 exons,” said Chao. “Our minimum specifications guarantee that 90% of that 51 megabases of DNA sequence will be covered at adequate depth to reliably detect a heterozygosity variant. In actuality, our coverage typically far exceeds that.”

► Moving into Clinical Practice

Wenqi Zeng, Ph.D., Ambry’s Director of Clinical Genomics, points out that exome sequencing has significant clinical advantages. “We’re now finding the cause of the disease much faster because we are able to look into the patient’s blueprint,” she said. “This is essentially a human genome project for an individual patient.”

The announcements by Ambry and Emory show that exome sequencing—which was first offered commercially for clinical diagnosis last year—is entering medical practice. Researchers at Emory Genetics Laboratory say that exome sequencing can be a cheaper, faster, and more efficient way to read the parts of the genome believed to be the most significant for diagnosing disease. The Emory lab is preparing to offer exome sequencing as a clinical diagnostic service.

Baylor College of Medicine (BCM) in Houston, Texas, launched whole exome sequencing (WES) for clinical diagnosis in October 2011. That makes it one of the first labs to offer WES for clinical diagnosis. So far, BCM has received nearly 100 samples for WES from patients with constitutional disease, such as those with intellectual disabilities, neurological disorders, and congenital anomalies of unknown cause.

► Next-Gen Sequencing

BCM’s new Cancer Genetics Laboratory (CGL) offers next-generation sequencing for a panel of key cancer genes that include many clinically actionable mutations. “We use this technology because of

its high sensitivity, fast turnaround time, and low cost,” said CGL Lab Director Marilyn M. Li, M.D.

“A physician who has a patient with colon cancer or breast cancer needs to know how to treat that patient right away,” she added. “Each cancer is time sensitive and a stat case. Having the ability to use next-gen and exome sequencing technologies to deliver a faster and more accurate diagnosis to the physician can mean the patient gets the right drug in time to save that patient’s life.

“However, mutation detection using next-gen panel sequencing is limited to the genes/mutations targeted,” Li said. “It would be ideal to use both targeted panel sequencing that offers high sensitivity and fast turnaround time and whole exome or whole genome sequencing that provides a more comprehensive landscape of the cancer genome. The need for cancer WES is obvious and BCM will launch cancer WES soon and offer both a next-gen panel and WES to cancer patients.”

Ambry’s Chao agreed that faster time-to-answer is a major benefit of the newest gene sequencing technologies. “Until very recently, sequencing large amounts of DNA was both time and cost-prohibitive,” she commented. “Next-generation sequencing technology has changed that. It has made large gene testing panels—including more than 20,000 genes in exome testing—a reality.

► Tapping the Potential

“Now, the potential for exome sequencing is enormous,” she added. “We anticipate a time when superior analytic validity, decreased costs, and rapid turn-around time will make exome sequencing the test of choice in genetics.”

TDR

—Joseph Burns

Contact Ambry’s Jeff Owen at 949-900-5542 or jowen@ambrygen.com; Marilyn Li, M.D., at 713-798-7427 or mmli@bcm.edu; Jean Pierre Issa, M.D., at 215-707-4307 or jpissa@temple.edu.

INTELLIGENCE

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



Like a tenacious bulldog, **Roche Holding AG** continues its determined effort to acquire **Illumina, Inc.**, the company that makes gene sequencing systems. Last week, Roche increased its offer from \$44.50 per share to \$51 per share for Illumina stock. That raises the price Roche says it will pay to \$6.5 billion, which is 15% greater than its original offer. It was on January 25, 2012, when Roche announced its tender offer for Illumina, at a price of about \$5.7 billion. (See *TDR, January 30, 2012.*) For its part, Illumina has not warmed up to the proposed acquisition.

»» MORE ON: Illumina

Two things are most likely to happen. First, Roche has a history of making unwelcome takeover offers, then raising the price to aggressive levels. This was the case back in 2008, when Roche ended up paying \$3.4 billion for **Ventana Medical Systems, Inc.**, a histopathology company with annual revenue of about \$290 million. Second,

should Roche successfully acquire Illumina, it would give Roche a commanding position in the fast-evolving market for next-generation gene sequencing and whole human genome sequencing. As the world's largest *in vitro* diagnostics (IVD) manufacturer, it can be assumed that Roche wants to maintain that position even as molecular and genetic technologies transform the clinical lab testing marketplace.

»» DEMAND FOR MT SCHOLARSHIPS GROWS 70%

Since 2003, **Siemens Healthcare Diagnostics** and the **American Society for Clinical Pathology (ASCP)** have worked together on an annual scholarship program directed at undergraduate and graduate medical laboratory students. In announcing the 100 winners of scholarships for the 2011-2012 academic year, the two organizations noted that the number of applications for these scholarships has increased by 70% in the past 24 months. This statistic reflects a

growing interest in laboratory medicine degrees and may be an auspicious sign that a career in laboratory medicine is gaining favor among young people of college age. Siemens and ASCP awarded a combined total of \$182,000 for this year's scholarship winners. Eligible students in the U.S. who are pursuing associate, baccalaureate, or master's degrees in medical laboratory science can qualify for these scholarships.



DARK DAILY UPDATE

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

...how the **American Hospital Association (AHA)** says Medicare's value-based purchasing program could put hospital revenue at risk. This could cause hospital lab budgets to be further squeezed.

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

*That's all the insider intelligence for this report.
 Look for the next briefing on Monday, April 23, 2012.*

**Make Plans
Now!**

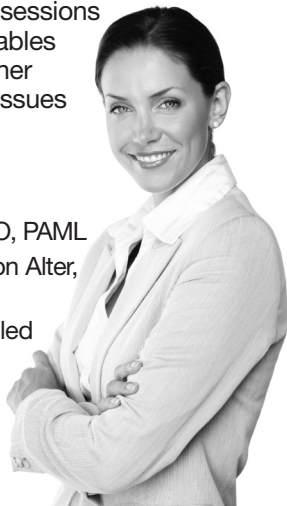
EXECUTIVE WAR COLLEGE

May 1-2, 2012 • Sheraton Hotel • New Orleans

Join Us for Industry-Leading Roundtables!

Our roundtables are becoming “must-attend” sessions at each year’s *Executive War College*. Roundtables are led by industry innovators and bring together executives for candid discussion of common issues and opportunities:

- **Lab CFO Roundtable**, led by Francis Imada, CFO, Clinical Laboratories of Hawaii
- **Lab CIO Roundtable**, led by Sonny Vardan, CIO, PAML
- **Lab Sales Manager Roundtable**, led by Jason Alter, Ph.D, Sales VP, Iris Personalized Medicine
- **Academic Pathology Chairs Roundtable**, led by James Crawford, MD, PhD, North Shore-Long Island Jewish Health System



Check for program details and to register.
visit www.executivewarcollege.com

UPCOMING...

- **Problems in Lab Testing for Pain Management: Why Federal and State Attorneys Are Investigating.**
- **Inside One Health System’s ACO: Early Evidence That Physicians Will Utilize Lab Tests Differently.**
- **Disruptive Technologies in Laboratory Automation and Point-of-Care Testing (POCT).**

For more information, visit:



www.darkreport.com

Sign Up for our FREE News Service!

Delivered directly to your desktop,
DARK Daily is news, analysis, and more.

Visit www.darkdaily.com

