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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

Information is Power for Lab Leaders!

YOU'VE ALWAYS RELIED ON THE DARK REPORT to keep you at the cutting edge of developments in laboratory management and the broader healthcare system. We've consistently been first with the essential, intelligence, and analysis you need to keep your laboratory at its financial and clinical acme.

Once again, in this issue of THE DARK REPORT we are first to identify and describe a trend which already touches large numbers of hospital and health system laboratories in the United States. Even though the majority of hospitals have yet to experience a crash in inpatient admissions or higher levels of patient bad debt, they are in a cash conservation mode! It's causing hospital labs to pull in spending. You can learn why by reading the intelligence briefing on pages 3-6.

You and I probably agree that leadership and management success are closely-linked to having access to timely, high-quality information. That is one reason why you rely on THE DARK REPORT for relevant alerts and market insight unavailable from any other source in our industry. Because our country is now in the midst of an unprecedented economic decline, it becomes even more important for you and your laboratory team to have rational, detailed intelligence on unfolding events.

At THE DARK REPORT, our response to the deteriorating economy and the probability of major healthcare reform legislation is to recast the upcoming *Executive War College on Lab and Pathology Management* to provide you with up-to-the minute insights and strategies. This highly-respected gathering of national and global lab industry leaders is now focused on the current critical issues linked to unfolding economic and political events.

If you agree with me that "knowledge is power", then you will want to be with us at the 14th Annual *Executive War College* in New Orleans on April 28-29. Expect to learn the latest from Washington insiders about the likely direction for healthcare reform, how it may positively or negative affect laboratories, and ways that you might shape the debate. Hear from labs that are implementing strategies to conserve cash, improve productivity, and refocus outreach sales to sustain profitable new business.

Am I asking the impossible? With hospitals capping travel and education spending, that may be true. On the other hand, true leaders always find a way to get the information they need to make the right decisions. That is why I hope you convince your administrators that this *Executive War College* is a good investment—a "must attend" opportunity for you to learn and to bring back strategies that generate huge savings for your lab and hospital! TDR

Unprecedented Times Lie Ahead For Labs

Start with the huge financial hit to hospitals, which has slowed capital spending by laboratories

CEO SUMMARY: Here's a lab industry first: insight and analysis about why hospital/health system laboratories are already feeling the financial pinch as their parent organizations scramble to conserve and accumulate cash. That's bad news for IVD vendors and other lab industry suppliers. And that's not all! Healthcare reform proposals carry the potential to further hamstring the finances of clinical labs and pathology groups.

IT'S A TIME WITHOUT PRECEDENT for clinical laboratories and pathology groups in the United States. Unfolding events will challenge pathologists and lab managers in serious ways.

The first, and most immediate, development is the collapse of equity values and the stock market following the mortgage crisis and widespread failures of banks and financial companies over the past six months. These events significantly damaged the financial integrity of most hospitals and health systems. However, this remarkable development has generally been unreported by the media and healthcare publications.

With this intelligence briefing, THE DARK REPORT is first to alert the laboratory industry of a broad trend that has direct impact on hospital laboratories, along with the industry vendors who sell them analyzers, reagents, and supplies. Simply put, hospitals and health systems are reining in spending as they strive to rebuild cash reserves. Consequently, hospital labs are facing unexpected demands to curtail scheduled capital spending. That allows hospitals and health systems to move that capital into cash accounts.

As well, hospital labs—along with other clinical departments—are also being asked to prune spending below budgeted levels and deliver that additional cash back to the parent hospital. Again, hospitals and health systems are using this cash to increase total cash-on-hand.

For the immediate future, this puts many hospital laboratories in a "cash preservation mode" so as to support the financial priorities of their parent hospitals or health systems. The implications of this

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SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes *THE DARK REPORT* plus timely briefings and private teleconferences, is $13.10 per week in the US, $13.70 per week in Canada, $14.85 per week elsewhere (billed semi-annually).

situation for the greater laboratory industry are unclear.

However, it is easy to understand why this spending roadblock occurred. These actions are a direct consequence of one single development: the collapse in the value of equities and financial instruments during recent months. Headlines have screamed the news that investors and individuals in the United States have seen the value of their investments fall by 30%, 40%, 50% or more!

50% Drop In Portfolio Value

Like investors and individuals in the United States, hospitals and health systems have seen equally devastating reductions in the value of their endowments and investment portfolios. A health system with an investment portfolio valued at $1 billion in January 2008 may have only $500 million or $400 million in value today.

This has created an unexpected financial problem for any hospital and health system with bonds or debt that must be serviced (and that means almost every hospital in this country). Typically a bond issue requires the hospital to maintain a cash reserve that equals a specified number of days of average revenue—often as high as 180 days. If the hospital does not maintain the required cash reserve, it violates its bond and/or debt covenants. Once declared in default of that covenant, the lender can assess financial penalties and raise the interest rate. This increases the amount of money the hospital/health system must pay to service its bonds and debts.

Loss Of $60 Million Per Year

Take this example: assume a $1 billion investment portfolio for the hospital during 2007 that earned an 8% return. That hospital received $80 million in income during the year (or $6.8 million per month). This income was available to keep cash-on-hand at the level required by the hospital's bond covenants.

Now, since last fall, assume this investment portfolio dropped in value by, say 50%. Also, assume the return fell from 8% to 4%. Thus, the $500 million portfolio now produces only $20 million per year in income (or $1.7 million per month) to the hospital.

In this example, the hospital has seen a $60 million reduction in annual income, in just over the past six months. It needs to replace this lost cash flow from other sources. One fast way to do that is to defer capital spending and to ask hospital departments to cut discretionary spending below budgeted amounts wherever possible.

This dramatic setback in hospital finances has gone unremarked by the press for a simple reason. At the same time that hospital investment portfolios have lost 50% of their value, most of these same hospitals continue to experience a constant rate of inpatient admissions.

Reporters usually check hospital admission rates to see if rising unemployment and/or consumer spending cutbacks are causing a decline in inpatient admissions. Thus, by watching inpatient admission rates and not the financial condition of hospitals' investment portfolios (and income from investments), reporters have missed this story.

Parsimonious Lab Spenders

There will be no quick and easy recovery from this situation. That's because hospitals/health systems, having lost 50% or more of the value of their investment portfolios and endowments, will not soon recover that value. As a result of this situation, THE DARK REPORT predicts that hospital laboratories will be parsimonious spenders during the next 24 months.

The next trend which bears watching is consumer response to the deteriorating economy. Will consumers cut back on healthcare spending? Will growing ranks of unemployed cause bad debt levels to increase—not just for hospitals, but also for laboratories and pathology groups?

Unfortunately, signs point to tougher times ahead. The most obvious factor is this

nation's worst economic downturn since 1982-83. Every week brings another round of bad news about economic indicators. It was last fall when years of over-stimulation in the real estate and mortgage industry finally caused the bubble to burst.

In the months since then, major companies in the banking and financial sectors collapsed. Unemployment rates began climbing as companies laid off employees in response to falling demand for their products and services.

Stock Market Declines

Even the inauguration of a new president and a new Congress last January brought little good news. In response to the first economic stimulus bills passed by lawmakers, stock market values collapsed, falling to levels not seen in 12 years!

For that reason, THE DARK REPORT considers the free fall of the Dow Jones average from 13,000 to under 7,000 over the past year as an inauspicious development. The world's smartest economic and financial minds—who are paid to put money where it will earn the highest return—are avoiding the stock market. That is their vote of "no confidence" as to the expectation that recent federal actions will "stimulate" the economy.

Business Strategies For Labs

It is necessary for laboratory administrators and pathologists to establish an accurate perspective of current and future economic and political issues. That context then guides efforts to develop appropriate business, financial, and clinical strategies for their clinical laboratories and anatomic pathology group practices.

What will make the coming economic times particularly challenging for many younger lab managers is that they have never worked in a laboratory during an economic recession. It was 1982-83 when the last deep recession dogged the American economy. For this reason, these younger lab executives and pathologists lack the

"Crises Strategies" for Labs At Upcoming War College

THIS ECONOMIC DOWNTURN is already being compared to the Great Depression of the 1930s! Many veteran lab administrators and pathologists are preparing their labs and pathology groups for tougher times ahead.

That makes this year's ***Executive War College*** in New Orleans on April 28-29 the first major laboratory event to provide intelligence and analysis about these remarkable trends. Speakers and special sessions to help lab directors and pathologists respond to these new challenges are a core part of this year's curriculum.

For example, Alan Mertz, President of the **American Clinical Laboratory Association** (ACLA) of Washington, DC, will provide an important perspective on the expected healthcare reform legislation. He'll offer an "inside the beltway" perspective, identifying the new powerbrokers in healthcare reform and how legislation currently being drafted is likely to either benefit or disadvantage lab testing services.

Another important 'inside the beltway" perspective will be provided by Peter Kazon, Attorney at **Alston & Bird** in Washington, DC. Kazon is one of the nation's recognized authorities on legal, regulatory, and legislative issues in laboratory medicine. He will identify evolving new legal threats. He'll also handicap the new powerplayers in Washington and how they may help or hinder the fortunes of laboratories in the political dealmaking now commencing.

In the midst of the first serious, extended economic downturn since the first half of the 1980s, this ***Executive War College*** is designed to be every laboratory manager's single most valuable resource. It will prepare lab leaders to weather approaching financial storms. It will provide powerful strategies that laboratories and pathology groups can use to protect cash flow and win profitable new business.

experience and perspectives accumulated by their older colleagues during that time.

Crystal Ball Gazing

Knowing the dangers of consulting its crystal ball, THE DARK REPORT offers some predictions about how the laboratory industry is likely to fare during the next couple of years. These prognostications are offered as a basis to stimulate discussion among the management teams of clinical laboratories and pathology groups. Every city and every region will have a different experience to the unfolding economic and political events. (And, that is TDR's first prediction!) For that reason, it is important that individual labs craft business, financial, and operational strategies that are appropriate for their regional service area.

Prediction: this nation is entering an economic and political cycle without precedent. Since last October, actions taken by Congress and the federal government have dwarfed, in spending scale and adjusted for inflation, anything seen since federal spending during War War II. Thus, using past experience as a guide for future actions is not likely to be productive.

Prediction: Baby Boomer and Generation X patients will continue to demand access to healthcare services and the newest technology, whether genetic lab tests or new, expensive therapeutic drugs. It will be difficult for lawmakers to limit consumer access to such health services, because these consumers vote!

Strong Labs To Prosper

Prediction: Clinical laboratories and pathology groups led by strong, visionary individuals will perform surprisingly well and are likely to emerge from the end of this economic cycle as profitable, larger organizations.

Prediction: Economic forces already in motion will cause the financially weakest hospitals to restructure, file bankruptcy, or sell themselves to stronger health organizations. Buyers will try to keep these weak hospitals open and operating, but if the economic malaise lasts long enough, many of these hospitals will be closed.

Prediction: If hospital labs defer capital purchases long enough, this will put financial stress on smaller *in vitro* diagnostics (IVD) manufacturers and suppliers. That will trigger further consolidation among lab vendors as strong companies acquire these financially-weakened companies.

Prediction: The longer that economic activity in the United States stays flat or declines, the more opportunities progressive labs will have with private payers. In particular, labs will find private payers more receptive to programs that help physicians do a better job of ordering and using lab tests that produce improved patient outcomes while lowering the overall cost per healthcare episode.

Prediction: There will be no slowdown in the introduction of advanced molecular technologies, particularly in laboratory medicine. During this economic cycle, a rapid pace of technology introduction will be sustained because of: 1) demand by patients; 2) opportunities for profit; and, 3) ready acceptance by clinicians. This is a another positive factor for innovative laboratories that continue to exploit strategic opportunities during this economic downturn.

Strategic Planning

Lab administrators and pathologists should use these predictions as a launch pad for strategic planning and crisis anticipation within their respective laboratory organizations. THE DARK REPORT is optimistic that laboratory testing's vital role—and huge leverage as an added-value service—will help the majority of laboratories survive whatever is to come.

However, the more important responsibility for lab administrators and pathologists is to prepare their laboratories for the worst, while positioning their labs to prosper from the opportunities that continue to exist, even in difficult economic times. TDR

Lab Management Update

Cleveland Clinic Unveils Plan For New National Esoteric Lab

Target is to serve send-out testing needs of hospitals, health systems, and other labs

DESPITE A WORSENING ECONOMY, the **Cleveland Clinic** will begin construction of a major new $25 million laboratory facility of 100,000 square feet this summer. The lab is expected to open by the end of 2010.

During the past two years, Cleveland Clinic has quietly laid the groundwork to create a reference and esoteric laboratory testing business that will compete nationally for the send-out testing business of hospitals, health systems, and other laboratories. Last fall, Cleveland Clinic hired Dino Kasdagly away from **Mayo Medical Laboratories** to be Chief Executive Officer of this new laboratory business unit.

At a press conference on February 26, David Strand, Chief Operating Officer at the Cleveland Clinic, stated that the laboratory expansion is, "... about how we can export our expertise to other markets, how we take our intellectual property and utilize it ... [to] benefit the clinic."

Resources To Compete

THE DARK REPORT observes that Cleveland Clinic has the resources to become a serious national competitor. The Pathology and Laboratory Medicine Institute at Cleveland Clinic is already among the largest clinical laboratories in the United States. It performs 10 million lab tests annually, of which only 10% are for other hospitals. It has a staff of almost 800, including 59 pathologists.

Leadership at the Cleveland Clinic is optimistic about the opportunities for a new esoteric lab in the United States. "To give you perspective on the market, the esoteric space grows between 10% and 15% a year," stated Kasdagly in an interview with the *Cleveland Plain Dealer*.

That view was echoed by Kandice Kottke-Marchant, M.D., Ph.D., Chair of the Pathology and Laboratory Medicine Institute at the Clinic and President of the reference lab. "Medical knowledge now doubles practically every couple of years," she commented. "Some small hospitals can't bring these cutting-edge tests onto their clinical platforms fast enough."

Formerly in charge of information management in Mayo's department of laboratory medicine and pathology, Kasdagly will supervise the information technology infrastructure for the reference lab expansion. The new system eventually will include the ability to view digital images of pathology specimens transmitted from labs across the globe.

Cleveland Clinic is preparing to enter an intensely competitive sector of the lab testing industry. In the past 12 years, at least two other companies similarly launched efforts to grab share in the hospital/health system reference testing market. Cleveland Clinic may be banking on its national and international reputation as a source of competitive advantage that will allow it to profitably compete in this market sector. TDR

Olympus Diagnostics Unit Sold to Beckman Coulter

More consolidation among IVD companies as Beckman boosts its presence in chemistry

CEO SUMMARY: For Beckman Coulter, the opportunity to acquire the diagnostics business of Olympus Corporation was compelling for at least two reasons. One, the chemistry and automation products of both companies are quite complementary. Two, in a steadily-consolidating in vitro diagnostics (IVD) industry, Beckman's acquisition of the Olympus diagnostics unit was an important strategic response. It signals to financial analysts and laboratory customers that Beckman Coulter intends to continue as an aggressive competitor.

COMPELLING MARKET FORCES were in play when **Beckman Coulter Inc.** announced on February 27 that it would acquire the diagnostics business of **Olympus Corporation**.

Beckman Coulter, based in Yorba Linda, will pay about $800 million (or 77.45 billion yen) for the diagnostics systems portion of Olympus Corporation of Tokyo. The transaction is expected to close in the third quarter of 2009.

Beckman Coulter believes that, for its next full fiscal year, the addition of the Olympus Diagnostics business will generate an additional $500 million in revenue. It also expects that operating income will increase by $40 million to $50 million.

The Consolidation Factor

This acquisition is another major event in the ongoing consolidation that has reshaped the *in vitro* diagnostics (IVD) industry over the past 15 years. Once Beckman Coulter finalizes its purchase of Olympus, it will mean one less vendor for chemistry systems in the clinical laboratory marketplace.

It is Olympus' strengths in clinical chemistry systems that appealed to Beckman Coulter. "We think this is a terrific combination," said Mike Renard, Beckman Coulter's Vice President of Business Development. "The way our chemistry businesses complement each other on a customer level and on a product level is significant."

Olympus has been successful at placing its chemistry products in laboratories that handle high volumes of testing. Thus, once the purchase is completed, Beckman Coulter gains access to these highly-desired laboratory customers. It sees an opportunity to sell these Olympus chemistry customers other products from the Beckman Coulter portfolio. "This acquisition broadens our chemistry offering, particularly to the largest hospital laboratories," noted Renard. "Further, these Olympus customers represent a valuable new customer set for Beckman Coulter's entire range of immunoassay products."

Beckman Coulter further believes there is additional synergy between the

product lines of the two companies. "Our automation product lines are complementary," he continued. "We're particularly strong in total laboratory automation (TLA) and Olympus is recognized for its pre-analytical automation. This will enable us to offer customers more automation choices and different combinations to fit the unique needs of their clinical laboratories."

Ongoing consolidation and the changing landscape of the IVD marketplace seemed to be a factor in Olympus' decision to divest its diagnostics business.

"For example, Olympus has a product called OLA," Renard added. "This is a front end handler and tube sorter for processing. That business is based in Germany, and we think it is very complementary to the full track systems that we have used, principally in the United States."

The Olympus acquisition is important to Beckman Coulter for another reason: it further expands Beckman's presence in Asia, where several countries have an accelerating demand for laboratory testing systems as their healthcare systems develop. In the next decade, countries such as China and India—with their huge populations—are predicted to be lucrative markets for the IVD industry. "We like the fact that this acquisition gives us access to a strong and loyal customer base," Renard commented. "Plus Olympus has a significant presence in laboratories in Europe, in Japan, and several other markets in the Far East."

IVD Industry Consolidation

Ongoing consolidation within the IVD industry was another factor in Beckman Coulter's decision to acquire Olympus. The company recognized that size, scale, and a broad, integrated product offering are keys to success in the global IVD market. From that perspective, acquiring Olympus helps Beckman Coulter on each of those points.

"In recent years, consolidation in our business has been significant," stated Renard. "**Seimens** and **Roche** are good examples. Both companies have used acquisitions to expand product offerings and scale."

Ongoing consolidation and the changing landscape of the IVD marketplace seemed to be a factor in Olympus' decision to divest its diagnostics business. As reported by *Kyodo News International* of Tokyo, Japan, although Olympus recognized that its diagnostics business operated in the black, intensifying competition among IVD manufacturers meant the company would be better off divesting its IVD business. Olympus says it will concentrate its business resources on what it perceives to be its core competencies, such as business lines in digital imaging and endoscopy.

Integrating Sales, Marketing

Lab administrators and pathologists know that consolidation and acquisitions involving their IVD suppliers often trigger changes. That will be true of the deal between Beckman Coulter and Olympus. Post-acquisition, Beckman Coulter will want to eliminate redundant costs and begin melding the two organizations into one. "We are looking at synergies and have established a team that is working on integration plans," stated Renard. "But at this point, it is premature to speculate on any outcomes from that planning process."

By its acquisition of the diagnostics business of Olympus Corporation, Beckman Coulter has made a strategic move long anticipated by Wall Street analysts. It has also signaled its intent to do what is necessary to continue as one of the world's top-tier manufacturers of *in vitro* diagnostics products. TDR

Contact Mary Luthy at Beckman Coulter at 714-773-7964 or mluthy@beckman.com.

Resolved 10-Year Issue of Hemolyzed ED Specimens!

Boston's Beth Israel Scores Improvement Gains with Lean

CEO Summary: Lean methods are helping laboratories resolve aggravating problems that have been unresolvable for as long as 10 years. At Beth Israel Deaconess Medical Center in Boston, improvement teams involving the laboratory and ED staff addressed high rates of hemolyzed specimens. Collaboration among departments and the use of Lean methods produced swift results. The rate of hemolyzed specimens collected in ED has fallen dramatically and now is comparable with rates across the entire hospital. Even the Beth Israel CEO has celebrated this success.

LAB DIRECTORS ARE WELL AWARE of problems that can develop between the laboratory and other departments in a hospital. Often one department has a procedure that makes it difficult for the other to do its job efficiently.

Last fall, **Beth Israel Deaconess Medical Center** (BIDMC) in Boston set out to solve two such problems. In each case, BIDMC used Lean techniques to identify solutions and produce lasting results. What makes this case study particularly interesting is that both problems are common in hospital settings across the nation—but the solutions were unusual!

Further, these projects attracted the attention of the hospital's CEO. He bragged about the two successful efforts involving the laboratory in his blog posting.

One problem centered around higher than normal hemolysis rates for patients in the emergency department who had potassium draws. The other problem involved requiring couriers to follow a needlessly long and confusing process to log patient samples collected in the gastroenterology suite.

The noteworthy elements of this case study are the use of Lean methods to identify solutions and the resulting partnership that developed between the laboratory and the other departments in the hospital. In fact, Gina McCormack, the lab's operations director, believes partnerships the lab developed with the ED and GI departments are perhaps the most significant result from the entire process.

BIDMC has 621 licensed beds. Its emergency rooms has about 140 patient visits each day. A teaching hospital of **Harvard Medical School**, BIDMC is a Level 1 Trauma Center. The lab does 6 million billable tests annually.

McCormack described the hemolysis issue for patients in the ED. "This problem has existed for 10 or more years and has been the subject of many discussions during that time," she said. "In the lab, we were confident we understood the source of the problem. But whenever we tried to tell ED staff how to solve these problems, we got nowhere. We would say, 'This is what the problem is and you create more work because you try to avoid peripheral needle sticks. Yet, in fact, you are sticking people unnecessarily.' This is because ED nurses commonly used IVs when drawing potassium samples from patients."

One measure of quality in any ED is the hemolysis rate, meaning the number of defective specimens compared with the total number of specimens drawn. Hemolysis can skew a patient's test results, thus requiring a redraw and retest.

Hospital CEO's Blog

BIDMC's President and CEO, Paul Levy, in his blog, "Running a Hospital," wrote last fall that, "the hemolysis rate for lab specimens collected in the ED was found to be 22.4%, approximately five times their counterparts on the inpatient units (3.9%). This rate had several deleterious effects: patients' hemolyzed specimens often had to be recollected and retested, therefore these patients had to wait on average 56 minutes longer for lab results, and frustration levels in both the ED and the laboratory were high."

As Levy explained, hemolysis can result from improper specimen collection. Decreasing this rate would improve ED throughput, cut patient length of stay, and improve patient satisfaction. But also, cutting the hemolysis rate would reduce the need for recollections, along with savings in both time and materials.

"Rework is frustrating for everyone, particularly for patients," McCormack commented. "When the specimens have to be recollected and retested, those patients must wait, on average, 56 minutes longer for lab results. The protocol in our laboratory is that if we get a critical value for a certain test—whether it is hemolyzed or not—we will repeat the test, document it, and flag it for discussion. We call it to the attention of the ED, and follow the critical value policy of writing it down and reading it back and then documenting these steps in our computer system, all of which involves increased steps and work.

"We knew everyone was well intentioned, and that everyone wanted to deliver the best care, but the ED wanted to do

specimen collection a little differently," she said. "To discuss the problem and work together on a solution, we assembled a working team made up of staff from the lab, the ED, and any other department that was affected. In a kaizen event, over two or three days, we examined every step in the procedure of drawing samples in the ED.

"We learned, for example, that the ED staff was trying to be as efficient as possible," explained McCormack. "For their part, they learned that they didn't know the best procedure for collecting these samples. Next, our laboratory staff observed the processes for specimen collection used in the ED. That helped our lab staff learn how and why the ED was collecting specimens in this manner. For example, ED nurses used IVs to do the patient draws, which is a collection method that can increase the hemolysis rate."

"BIDMC's IV and phlebotomy experts do not recommend IV draws. Neither does the IV product manufacturer, in part because of the risk of hemolysis," she added. "Yet, the ED staff worried that they would be sticking each patient twice (once to set-up an IV and a second time to draw blood through venipuncture). Yet, almost 30% of the time, the IV method resulted in the need to stick patients twice because of hemolysis.

IV Draws And Hemolysis

"When we explained that IV draws have higher rates of hemolysis, the ED nurses said, 'That can't be the reason for the high rate of hemolysis experienced here in the ED. You would be having this problem elsewhere because a lot of people in the hospital draw through IVs.'

"It turned out that one other department takes samples with IV draws, but they draw for creatinine and kidney function tests, which aren't impacted by hemolysis," McCormack continued. "Because they weren't drawing the potassium test, this department was not getting requests for redraws, nor was this collection method creating extra work in the laboratory.

"We did a further investigation," she noted. "We studied all the sample draws for that department over a two-day period. We determined that the hemolysis rate was 30%! But, because this had no affect on the tests being ordered, and no adverse affect on patient care, it was not a problem.

Pivotal "Ah Ha" Moment

"That was the pivotal, 'Ah ha,' moment for our lab/ED improvement team," she added. "Both sides recognized the root cause of the problem. The nurses recognized that, although the practice of collecting blood specimens via the IV was motivated by doing the best for patient care, it was a practice that produced a high rate of hemolyzed specimens. In turn, that meant a redraw for about 30% of their patients—generating the second needle stick that they had been attempting to avoid!"

After two days of analyzing the problem and doing root cause analysis, McCormack says that a very thorough exchange of ideas took place. Agreement on new procedures was accomplished with much harmony and collaboration. "To stop collecting blood specimens at IV insertion, BIDMC assigned ED technicians to draw all blood," stated McCormack." "Under the revised ED protocol, ED techs can draw *only* via venipuncture. At the same time, BIDMC's phlebotomy team retrained the ED techs according to the pathology department's venipuncture standards."

Once the new process was implemented, McCormack reviewed the results. "Since we did this work flow redesign, the hemolysis rate in the ED is consistently about 6% or 8%," she said. "This is the normal rate for every department in the hospital because, even when a specimen is drawn the right way, it can hemolyze. It's just a fact of life.

"What is significant is that the hemolysis rate in the ED now matches the hemolysis rate for the rest of the hospital," explained McCormack. "There is now a benchmark rate for the ED. Even better,

our laboratory has a much stronger and productive relationship with ED staff. By itself, that is a powerful result. Another notable outcome is that the process was mutual and collaborative between the laboratory and the ED. "

Lean methods for process redesign also played a key role in resolving another ongoing problem at Beth Israel Deaconess Medical Center. The second problem involved transport of patient specimens from the gastroenterology suite to the laboratory. Again, McCormack was on the Lean improvement team that reviewed the previous process and recommended a new one.

"Our approach in this problem-solving project was different than the step-by-step analysis of work flow conducted by the entire team in the kaizen project to reduce hemolysis rates from specimens collected in the ED," noted McCormack. "For the GI project, the Lean team designated specific individuals to do what's called 'value capture.' We actually partnered with a company called **Value Capture, LLC**, in Pittsburgh, Pennsylvania. They documented all steps in the process being studied. Each step was evaluated, then a report was made to the entire Lean team.

Transport From GI Suite

"The problem occurred when transport picked up specimens at the GI suite to bring them to the laboratory" McCormack explained. "In the GI suite, GI staff would put the specimens in a bag. Next, staff would write on a log sheet what specimens should be in the bag. The problem hinged around a major complication.

"Early each day, GI staff prepared the log sheet, with each patient listed by time of appointment," recalled McCormack. "However, during the day, patients were not served in alphabetical order. Thus, when transport arrived several times over the day to pick up specimens, it was difficult for transport to acknowledge which specimens were in the bag and which specimens belonged to a specific patient. Our first improvement was to put the log sheet in alphabetical order.

"When Beth Israel Deaconess operated two GI suites, this process was onerous but doable," McCormack added. "However, that changed when the two GI suites were combined into one. A single transport person was required to sort out all these matters. For them, it became a regular nightmare, experienced several times daily and was a significant reason for all sorts of problems further downstream as GI specimens reached the laboratory.

'The improvement team identified a number of issues,'" stated McCormack. "One, steps for transport to sign out each individual specimen were unnecessarily

Hospital President Lauds Lean Project of Lab & ED

IN HIS BLOG "RUNNING A HOSPITAL," Paul Levy, President and CEO of Beth Israel Deaconess Medical Center, recognized the Lean improvement project to address hemolysis in emergency department specimens.

The laboratory and the emergency department (ED) came together. Levy wrote that "each area owned this problem and for various reasons wanted to find a solution. The lab would have fewer critical values to repeat, call, and document. The ED would have fewer patients to re-stick, faster results, and happier patients." Levy noted that the following was learned and communicated to the respective Lab staff and ED staff:

- Long tourniquet time (>1 minute) increases hemolysis.
- IV product manufacturer does not support blood draws from IV equipment.
- Medical center IV and phlebotomy experts do not teach or recommend IV draws.
- Most ED staff worried about sticking the patient twice (once to set-up an IV and again to draw blood through venipuncture)—creating a negative experience for the patient. However, almost 30% of the time they did stick people twice due to hemolysis which created a 56-minute delay.

time consuming. Two, paperwork to accompany each specimen was not always completed by GI staff in a timely or uniform manner. Three, there was no reconciliation when GI specimens arrived in pathology. Four, there was no feedback about missing specimens. Five, not all required steps were standardized.

The Value Capture Process

"This Lean team was made up of individuals from GI, nursing, administration, pathology, transport, and Value Capture," she related. "We had the Value Capture people analyze the steps. Our team then devised a series of procedures that eliminated use of the log sheet with the alphabetical list of names. Instead, GI staff listed patients on the log sheet as each patient's samples came out of the suite.

"Another change was to put each patient's sample in a clear plastic bag that showed the number of specimens from each patient," she continued. "The transporter would collect the samples at the GI suite, note the number of samples for each patient, along with the name of the patient. As these specimens were delivered to pathology, staff there would receive each sample and note the number of tubes from each patient. These were simple steps, but they markedly improved the accuracy and productivity of this work flow.

"As part of the work flow redesign, the Lean team had the specimen tracking book moved to a more convenient central location in the GI suite, reducing delays," McCormack said. "One nurse in GI was designated to identify all specimens. Also, the transporter no longer needed to sign out each individual specimen by patient name."

Cutting Transport Time

Improvements were swift and substantial. "The result was a reduction of 57% in the amount of time between when a GI specimen was ready for transport and when transport arrived to pick the specimen up," commented McCormack. "There was an overall reduction of 61% in the time it took to transport GI specimens to pathology. The new work flow freed up hours of transport time, improving productivity and reducing the cost of transport. There was improved patient safety and quality was maintained."

These Lean process improvement successes at Beth Israel Deaconess Medical Center demonstrate how many of the nation's most respected hospitals have embraced Lean and similar quality management methods. Equally notable is how use of Lean in cross-disciplinary improvement teams created the communication to resolve the ED hemolysis issue—an issue that had eluded resolution for 10 years! TDR

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Mayo Clinic Uses RFID tags To Track GI Samples to Lab

OTHER HOSPITALS HAVE THE PROBLEM OF FINDING THE BEST WAY TO identify and track samples from the gastroenterology suite to the pathology department. In January 2007, **Mayo Clinic** of Rochester, Minnesota, announced that it would begin using radio frequency identification (RFID) tags to track biopsy specimens from its 41 operating rooms to pathology. As many as 20,000 endoscopy and colon procedures are done annually in these operating rooms. *(See TDR, January 29, 2007.)*

THE DARK REPORT noted, at the time, that Mayo's use of RFID to track lab specimens was an important technology breakthrough for the lab industry. RFID has the potential to improve laboratory operations and work processes in many ways.

Mayo's decision to deploy RFID in this manner followed a five-month pilot program in 2006 that used RFID tags and scanners manufactured by **3M Corporation**. The pilot program involved five GI operating rooms and one laboratory. Mayo tracked 1,800 tissue samples from the surgery suites to the lab. Benefits identified during this pilot program were increased productivity, fewer errors, and improved patient safety.

Competition in Rapid Tests Means Value to Labs

As number of rapid test solutions increase, IVD manufacturers look for ways to add value

CEO SUMMARY: One of the hottest market segments in in vitro diagnostics (IVD) is rapid testing. However, because labs now often have multiple choices when selecting a rapid test, IVD manufacturers recognize the need to differentiate their products by adding additional features and benefits. In the case of 3M's new rapid test for influenza, the ability of the system to deliver results directly into the laboratory information system is one such product differentiator.

ONE SIGN THAT THE MARKET for rapid testing is maturing is when *in vitro* diagnostics (IVD) manufacturers position their test kits with multiple features that promise to add value to laboratory customers.

That seems to be happening in the market segment of rapid testing for influenza. This is a sizeable market, since up to 20% of the U.S. population will suffer a case of influenza during the course of a year. Influenza is the cause of more than 200,000 hospitalizations and approximately 36,000 deaths annually.

Influenza Test Kits

Currently several manufacturers offer test kits for influenza, expanding the choices available to laboratories. **3M Company** of St. Paul, Minnesota recognized this competition as it developed its own rapid test for influenza.

After an evaluation in one of the busiest virology labs in the country, 3M's new rapid detection flu test performed with sensitivity and specificity comparable or better than other FDA approved immunoassays, and produced results in 15 minutes. However, recognizing the need to differentiate its rapid flu test from competing products, 3M designed its analyzer and rapid flu test system to send results directly to a laboratory information system (LIS). The new test is the 3M Rapid Detection Flu A+B Test.

One of the laboratories which participated in the evaluation of 3M's rapid flu test was the **University of Rochester Medical Center** in Rochester, New York. Last year, the lab did 5,500 flu tests, about 10% of the total of 55,000 tests conducted in its virology lab, and just under 1% of the total 600,000 tests the medical center's microbiology lab did last year.

Given the volume of tests the lab does every year, Marilyn Menegus, Ph.D., Director of Rochester Medical Center's virus lab, was skeptical that this new rapid flue test would outperform the assays already in use at her lab, which included PCR testing. "Our lab evaluated it against two rapid tests and the direct fluorescent antibody (DFA) test," noted Menegus, "Our initial evaluation showed that the 3M Rapid Detection Flu A+B Test was as good or better than our other tests in

terms of specificity and sensitivity. Then over time, I saw that this rapid flu test had another advantage."

Utility for Remote Labs

"The test system can report results directly to the LIS," explained Menegus. "In settings like ours, where several remote laboratories may be performing rapid testing, a system like this eliminates all the subjectivity involved in interpreting the results.

"Once the test system is set up, it connects to the central computer and collects all the data from sites where it's running," she said. "Gathering data from remote sites is often problematic for lab directors. That's because remote labs often have many different individuals running the test and multitasking on a number of different applications. This test minimizes the chances for error because it reports the results directly to the LIS.

"We recognize that this assay suffers the same disadvantage as all immunoassays do in terms of detecting flu in that it is not as sensitive as cell culture," Menegus observed. "However, cell culture takes three days, and you can't do too much with a patient who has the flu if you have to wait for three days. When triaging patients or considering antibiotics, a 15-minute result is needed and I can't do that by any method other than the rapid assays.

Prescription Decisions

"A number of studies were done with other rapid flu tests and demonstrated that, if an answer is produced quickly, prescribing habits and other disease management decisions can be significantly influenced" she stated. "The big benefit with this new assay is that it determines whether it is flu A or B. Thus, it can help in determining which medication to prescribe."

The assay also was tested at the **North Shore Long Island Jewish Health System**, in Manhasset, New York. Christine Ginocchio, Ph.D., Director of Microbiology, Virology and Molecular Diagnostics at the health system, said, "Properly interpreting test results is critical, especially considering that most flu antiviral medications have a 48-hour recommended therapeutic window for prescribing. Thus false-positives or even delayed test results may result in misapplication of therapy or may reduce its effectiveness. Having an automated reader almost eliminates the potential for misinterpreting results, leading to a faster and more informed treatment decision, which results in better patient outcomes."

THE DARK REPORT observes that 3M's Rapid Detection Flu A+B Test System represents an example of how IVD manufacturers are working to pack more value into their test kits and testing systems. In particular, the ability of the system to feed results directly into the laboratory information system shows that IVD firms recognize the need of laboratories to reduce or eliminate any source of a potential error that could affect patient care. **TDR**

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Rapid Influenza Test Exports Data to LIS

ONE OF THE ADVANTAGES of the 3M Rapid Detection Flu A+B Test is that it can deliver results electronically within 15 minutes. 3M says the test represents the next generation of assays for the flu.

Requiring three minutes or less of prep time, the test can detect positive or negative results, differentiate influenza A from influenza B, and display the results on the 3M Rapid Detection Reader. In addition, the system allows labs to export the resulting data to a laboratory information system (LIS), reducing the potential for reporting error by eliminating the need for manual recording and transferring of results.

Aperio, Cerner Interface Digital Path and Path LIS

Interface allows pathologists to integrate digital pathology system with anatomic path system

CEO SUMMARY: For pathologists watching the market acceptance of digital imaging and digital pathology systems, another milestone has been reached. The nation's largest health IT companies are beginning to develop interfaces between their anatomic pathology laboratory information systems and digital pathology products. One such interface is now available to interface Cerner Corporation's CoPathPlus with the Aperio Technologies' Spectrum pathology (PACS) software.

DIGITAL PATHOLOGY SYSTEMS are evolving on a path that uncannily mirrors the evolution of digital radiology systems. Several developments in recent weeks confirm this fact.

One milestone in the market acceptance of digital radiology systems was the development of partnerships between radiology PACS (picture archiving and communication system) vendors and radiology information system (RIS) vendors. These partnerships emerged as the big health IT vendors recognized that sales of digital imaging products were accelerating and they needed to integrate these radiology imaging (PACS) products with their RIS offerings.

Now the same phenomenon is unfolding with digital pathology (PACS) systems and AP laboratory information systems (LIS). Last month, **Aperio Technologies, Inc.**, of Vista, California, announced the development of an interface with **Cerner Corporation** of Kansas City, Kansas.

One of Cerner's pathology laboratory information systems (AP LIS) is Cerner CoPathPlus. CoPathPlus can now interface with Spectrum, Aperio's digital pathology information management system which is essentially a pathology PACS. The interface between CoPathPlus and Spectrum is designed "to optimize workflow and facilitate access of digital slide images and case data between the two systems."

This arrangement is also significant because Cerner CoPathPlus has a large installed base. Susana Coelho, Cerner CoPathPlus Director, says about 500 of the nation's 3,300 pathology groups currently use CoPathPlus. Therefore, the interface between CoPathPlus and Spectrum opens up a broader market for Aperio.

Interface Agreements

Aperio has also developed interfaces with **IMPAC Medical Systems, Inc.**, whose AP LIS is Powerpath, and with **McKesson Corporation's** Horizon AP LIS. Collectively, these three interface agreements highlight that AP LIS vendors recognize the need to support the digital pathology systems that growing numbers of their anatomic pathology customers are purchasing.

Aperio CEO Dirk Soenksen said the interface between Cerner and Aperio is

significant because "getting the attention of a big company like Cerner to invest resources in building an interface means that they must view this interface as an important activity." he said. "A company of Cerner's size and scope constantly juggles thousands of requests from customers."

"The fact that Cerner dedicated resources to develop this capability shows that there is demand for this interface from its pathology customers," explained Soenksen. "That customer demand affirms what we see in the market ourselves."

Meeting Customers' Needs

Another factor driving the decision to create an interface between CoPathPlus and Spectrum is the need to support optimum work flow for the pathologist. Both Cerner and Aperio have a common motive to streamline the steps a pathologist must take to evaluate a case and sign out the report.

"This interface supports productivity and ease of use," observed Soenksen. "The pathologist doesn't need to have a glass slide in his possession. He or she can simply click on a digital slide from within CoPathPlus and begin viewing it on the monitor. Instant access to a digital slide archive is one way the interface increases pathologists' efficiency and save time."

Cerner's Coelho acknowledged that digital pathology is still early in its adoption phase. "Like the first radiology imaging systems, digital pathology systems will require time to become mainstream," she said. "However, the early adopters in pathology are clamoring for high quality and systems that give an immediate response. In response, Cerner is leveraging its relationships with technology companies, such as Aperio, to create those capabilities.

For Aperio's users, the two systems have three essential points of integration. "One point of integration is the ability to launch the Aperio image viewer from within CoPathPlus," stated Mark Wrenn, Aperio's Senior Manager, Professional Services. "The second is the ability to exchange data between the CoPathPlus database and the Spectrum database. Third is the ability to capture an image from a digital slide and incorporate it into a report to a referring physicians."

The integration of image analysis results into the LIS report represents a fourth future point of integration. Pathologists should expect to see relatively rapid acceptance of digital imaging solutions. Improving technologies will reinforce this trend. TDR

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CoPathPlus–Spectrum: Explaining the Interface

IMPROVING THE PATHOLOGIST'S PRODUCTIVITY and contributing to improved accuracy are important benefits from interfacing a digital pathology system with a pathology laboratory information system.

Alex Medas, Senior Software Architect for Cerner Corporation, explained how the interface works. "Our essential role is to incorporate digital slides into the pathologists' workflow—and that is the most complicated part of the interface," noted Medas. "Digital pathology slides in Aperio's Spectrum are first labeled by CoPathPlus with a two-dimensional barcode," he said. "The slide is then scanned by Aperio's slide scanner, which also decodes the barcode, and CoPathPlus processes the slide based on the barcode."

"To get digital slides organically incorporated into the pathology workflow, we created a protocol so that a pathologist working in CoPathPlus will never feel that he or she is looking and working with a foreign application," Medas continued. "This interface makes it look and feel as if the pathologist never left CoPathPlus. That's the whole idea: They don't need to jump back and forth. All the functions of the Aperio system are working under the supervision of CoPathPlus. At the same time, there is two-way communication between the two systems."

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

In the United Kingdom, there is an interesting development regarding anatomic pathology and clinical laboratory services. The trust which operates the famous 986-bed **Guy's Hospital** and 957-bed **St. Thomas' Hospital** has entered a joint venture with **Serco Group plc**. Effective February, 1, Serco now manages the 50-50 joint venture, which is called **GSTS Pathology**. All pathology and laboratory services for the two hospitals are managed by Serco. The 10-year management contract is valued at £250 million (U.S.$349 million).

MORE ON: Serco JV

Several aspects of this transaction are noteworthy. First, it is unusual for the UK's **National Health Service** (NHS) to outsource laboratory services in an arrangement like this. Second, the NHS did not select a laboratory partner, but chose Serco, which is a management company that holds other health management contracts with the NHS. Third, Serco stated that "In the wider market, GSTS Pathology will offer a range of innovative solutions for delivering high quality efficient pathology services suitable for other NHS organisations, the private sector and for customers outside of the UK." That indicates how Serco hopes to leverage this joint venture into additional laboratory and anatomic pathology arrangements.

TRANSITIONS

• **Laboratory Corporation of American** announced that its new Chief Medical Officer is Mark Elliott Brecher, M.D. He formerly served as Vice Chair of the Department of Pathology and Laboratory Medicine at the **McClendon Clinical Laboratories, University of North Carolina Hospitals**.

• Fast-growing **XIFIN, Inc.** of San Diego, California has two new additions to its executive team. Joining XIFIN as Chief Financial Officer is Steve Zaboni. He has a strong diagnostics background, having served in executive positions with **AviaraDx**, **Arcturus Bioscience**, **Sequenom**, **Behring Diagnostics**, and **Boston Scientific**.

• XIFIN's new Vice President of Marketing is R. William (Bill) Taylor. His career has been in the high tech industry, including positions with **Accelrys, Inc.** and **IBM's** software group.

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PREVIEW #2

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Alan Mertz of American Clinical Laboratory Association...

Barack Obama's Plan for Health Reform: Are Labs and Path Groups at Risk?

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