

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...

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Founder & Publisher



Like Lab Medicine, THE DARK REPORT is Changing

ANY PATHOLOGIST OR LABORATORY ADMINISTRATOR who believes there is a status quo in laboratory medicine is ignoring plenty of evidence to the contrary in the healthcare marketplace.

Radical evolution is altering the health insurance industry, for the second time in almost 20 years. The Internet and new technologies in computer hardware and software enable the American healthcare system to capture even more information in real time and feed it to clinicians, patients, and payers in ways that benefit everyone. Rapid advances in genetic science are another source of important changes that affect the pathology profession and the laboratory industry.

For our clients and regular readers, this is old news. Over the past 11 years, THE DARK REPORT has regularly been among the first to alert them to an unfolding trend, to inform them about a breakthrough in laboratory management, or offer them useful analysis about an under-reported story of significance.

As yesterday's status quo melts into tomorrow's brave new world, THE DARK REPORT must evolve and change so it can continue to serve you with timely business intelligence and useful management knowledge. That is the reason we launched the *DARK Daily* earlier this month. This is a daily e-briefing delivered directly to our member's e-mail address. Short, concise, and to the point, it is a new channel for us to bring you news and management wisdom, by using new Internet technologies.

Like you, we don't claim to understand how the dot-com world operates. Also like you, we recognize that growing numbers of consumers are using the Web as a primary channel for commerce, information, and communication. We do recognize that many of you are turning to the Web as your primary channel for information, to conduct business, and to communicate with others.

That is why we are changing our status quo. *DARK Daily* is our first step to serve those of you who are "Web savvy." It will evolve and improve over time, utilizing your comments and suggestions. To check it out and become a member, just go to www.darkdaily.com. I also encourage you to let us know how you like it—and any ideas you have to make it better! **TDR**

Increased Competition For Hospital Lab Referrals

It's getting tougher for national reference labs to win new clients and expand market share

CEO SUMMARY: *It's a buyer's market for hospital send-out testing because the supply of such tests exceeds demand. To fill excess capacity in their labs, some reference/esoteric lab companies are willing to offer rock-bottom prices to new clients. This situation is also motivating national lab companies to develop and offer additional services to clients as a way to differentiate themselves.*

THERE ARE PLENTY OF SIGNS that the supply of reference and esoteric tests exceeds demand. That is a situation which favors hospital labs, many of which enjoy lower prices and more "extra" services as national reference lab companies compete for their send-out testing.

This situation continues to validate a prediction made by THE DARK REPORT back in 1999. At that time, **Quest Diagnostics Incorporated** had just acquired **SmithKline Beecham Clinical Laboratories** and **American Medical Laboratories, Inc.** (AML) had become a new competitor for hospital send-out testing. These developments were disrupting the status quo, to the benefit of hospital laboratories interested in negotiating a better con-

tract for the reference and esoteric test referrals. At that time, THE DARK REPORT wrote that "during the next 24 months, there will be outstanding opportunities to shop these six reference/esoteric testing providers and negotiate a winning package. Like the television game show, it's a good time to declare 'let's make a deal'." (*See TDR, August 30, 1999.*)

Not only was that an accurate prediction, but seven years later competition in this market segment remains both sustained and intense. Many hospital labs have benefited from this situation by shrewdly negotiating contracts that lowered their cost of reference send-out tests, sometimes by substantial amounts.

Recent events provide evidence that the supply of reference and esoteric

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testing continues to exceed the demand for such testing from hospital laboratories. As long as this situation remains unchanged, it is a buyer's market and hospital laboratories will benefit.

Aggressive Test Pricing

What is true of today's marketplace for hospital send-out testing is that the major competitors are willing to be aggressive on the pricing they offer hospital laboratory clients.

Thus, the national reference/esoteric laboratory companies face a classic business conundrum: when all your competitors are selling at identical prices, how do you differentiate yourself with customers? Recent actions at **ARUP Laboratories, Inc.** of Salt Lake City, Utah, provide evidence that it is taking steps to differentiate itself in the market.

In July, it was widely reported that ARUP Laboratories had announced an agreement with **Mednet Services** of Allen Park, Michigan to provide consulting expertise in managed care contracting and similar outreach development issues to hospital laboratory clients of ARUP Labs, upon request of such labs. What went unremarked is that no ARUP clients were "in the queue" to engage Mednet in this fashion, nor have any clients been known to enter into a consulting agreement with Mednet since the relationship was made public.

Resource Pool of Experts

Rather, the motive in this business collaboration seems to be that ARUP Laboratories is assembling a resource pool of experts it can introduce to its laboratory clients to help those clients with different operational and management projects, including laboratory outreach programs. This is a strategy to differentiate itself as a reference/esoteric testing laboratory that can bring more than just a full menu of tests and low prices to the negotiating table. ARUP Labs believes it

can win new business by offering packages that include competitive prices for the send-out tests, as well as assistance in bringing specific resources to the client laboratory.

Other national reference/esoteric laboratory competitors are similarly working to develop services and products that allow them to offer more than just low price to hospital labs—and at the same time differentiate themselves in the marketplace. These are rational business responses to a marketplace where there is excess testing capacity among the leading competitors.

Thus, the national reference/esoteric laboratory companies face a classic business conundrum: when all your competitors are selling at identical prices, how do you differentiate yourself with customers?

Two examples demonstrate why the market for hospital send-out testing continues to be intensely competitive. In December, 2004, **Specialty Laboratories, Inc.** relocated into its new laboratory facility in Valencia, California. At the time of the move, Specialty was already posting red ink because its expenses exceeded revenue.

The cost of the relocation and the operating expenses of the new facility were additional reasons why Specialty Laboratories needed to bring in new accounts, increase specimen volume, and gain new revenue. As most laboratory directors and pathologists know, Specialty has continued to compete aggressively for new business and it is willing to offer attractive low prices to win new client accounts.

Just four months after Specialty Laboratories moved into its new laboratory, a start-up laboratory company

entered the national reference/esoteric testing marketplace. **American Esoteric Laboratories, Inc.** (AEL) of Nashville, Tennessee, commenced operations in April 2004. Its declared goal is to offer reference and esoteric testing services to hospital laboratories and certain specialists.

Built New Lab In Dallas

AEL added to the supply by building a new laboratory in Dallas and has sent sales reps out to beat the bushes for new business. The company has not said much publicly about the success of its sales program. On the other hand, it has acquired four lab companies since the fall of 2004. What makes these acquisitions interesting is that three of these labs provide routine testing services to office-based physicians.

The fact that AEL has acquired routine testing labs may be a sign that competition for new reference/esoteric specimens from hospital laboratories is making it tough for AEL to achieve its internal growth goals on the planned timetable. In order to have the specimen volume needed to produce the necessary economies of scale, it is acquiring regional laboratories that primarily offer routine testing to office-based physicians.

Supply Has Not Declined

There has been no major reduction to the supply side of the reference/esoteric testing marketplace since THE DARK REPORT made its 1999 prediction. In 2002, Quest Diagnostics purchased American Medical Laboratories. But no labs were closed and Quest converted AML's main lab facility in Chantilly, Virginia into an east coast reference/esoteric testing center.

In 2005, **Laboratory Corporation of America** acquired **Esoterix, Inc.**, which operated specialty testing labs in a number of cities. LabCorp has redirected and consolidated some of this

testing. The other significant change during these seven years was the entry of American Esoteric Laboratories into the market, which was a further expansion in the available supply of reference and esoteric testing.

It should also be noted that the supply of reference and esoteric tests has been expanded by the regular entry of smaller lab companies which offer a limited number of specialized reference and esoteric tests. Individually, these increases to the supply are relatively small. It is the cumulative addition of this supply which creates more pressure on the national reference/esoteric laboratory companies.

Continued Supply Glut

Collectively, the experience of the past seven years indicates that the over-supply of reference and esoteric tests is not likely to disappear in the coming years. Such a situation benefits hospital laboratories. It means they can continue to shop competing reference laboratories against each other. Because of the economics of laboratory testing, reference labs with excess capacity will have an incentive to bid work from new clients at marginal costs, as well as bundle other value-added services into their bid.

Is there a downside to this test supply glut for lab directors and pathologists? After all, any time a reference laboratory underprices its tests, it will generate insufficient revenue to cover its costs. Over time, service levels may erode, to the detriment of that lab's clients.

That is an acknowledged risk, with an offset. Over the past 15 years, whenever a national laboratory provider found itself in financial difficulty, it generally sold itself to a stronger laboratory that corrected the problems and maintained service. **TDR**

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Buyer of MDS' Canadian Labs Agrees to Pay C\$ 900 Million

Sale allows MDS to exit the lab testing market, aggressive bidding pushed the price to high levels

CANADA'S LARGEST CHAIN OF CLINICAL LABORATORIES will change hands in a deal revealed on September 7, 2006 by Toronto's *The Globe and Mail*.

MDS Inc. will apparently sell its diagnostics division to **Borealis Infrastructure Management Inc.**, a private equity group owned by the **Ontario Municipal Retirement Board (OMERS)**. The purchase price will be C\$900 million (US\$806 million).

This is a noteworthy development, for several important reasons. First, veteran lab industry observers consider the price paid by Borealis to be high. The MDS diagnostics division has annual revenue of C\$400 million (US\$358 million). Borealis is paying more than twice annual revenue to acquire a business that MDS wanted to sell because of its challenging financial prospects.

Important Development

Second, the sale is also noteworthy because the purchaser was not a company currently in the laboratory business. In fact, there were two investment groups that bid aggressively to buy the MDS diagnostics division. Borealis edged out another private equity firm that included **Macquarie Bank Ltd.** of Australia and **CML Healthcare Income Fund**, which owns Canada's second largest laboratory company.

Such intense interest by private

equity investors mirrors a similar trend in the United States, where equity investors have outbid laboratory companies when certain lab businesses have been put up for sale.

A recent example is the sale of **Spectrum Laboratory Network** in Greensboro, North Carolina to **Apax Partners, L.P.** last year. It was known that the two blood brothers were among the parties that participated in the sales process. (*See TDR, November 14, 2005.*)

Emerging New Trend

THE DARK REPORT believes that MDS and Spectrum are early examples of a developing trend within the laboratory industry. Equity investors are willing to pay strong prices to buy laboratory assets when they come to market.

Over the past 10 years, equity investors who funded laboratory start-ups in the United States have generally done well. So it is not surprising that, as existing laboratory businesses come to market, equity investors are willing to pay strong prices to outbid others and buy an existing lab company.

This could mean that, in coming years, the two blood brothers may be outbid by deep-pocketed investors anytime an attractive laboratory company comes to market. It could also mean that, if equity investors overpay for the labs they buy, the two blood brothers could benefit by picking up those assets on the cheap—albeit some years later. **TDR**

Some Random Insights About LabCorp's Thinking

LabCorp's new CEO and executive team offer perspectives on lab industry trends

CEO SUMMARY: *Having scooped up a number of mid-sized laboratory companies in recent years, Laboratory Corporation of America is working to integrate these operations and continue to expand its market share. In a recent conversation with financial analyst Bill Bonello of Wachovia Securities, LabCorp executives discussed a variety of topics and trends in the laboratory testing market.*

THERE'S A TRANSITION UNDERWAY in the executive suite at **Laboratory Corporation of America**. On January 1, 2007, David P. King will succeed Thomas P. Mac Mahon as Chief Executive Officer.

To learn more about David King's thinking about the laboratory marketplace and any new directions for LabCorp, **Wachovia Securities** Financial Analyst Bill Bonello recently traveled to Burlington, North Carolina. There he met with David King, as well as Brad Smith, Executive Vice President of Corporate Affairs; Brad Hayes, CFO; and Scott Fleming, Director of Investor Relations.

Bonello came away from this meeting with several interesting insights, ranging from LabCorp's wish to expand into new regional markets to its perspectives on trends in managed care contracting for laboratory testing services. For clients and readers of THE DARK REPORT, these insights provide a general sense of some directions LabCorp is likely to take when David King assumes his new duties as CEO.

"LabCorp expressed a clear interest to expand into several major urban markets," noted Bonello. "Although it is open to using lab acquisitions as a way to enter these markets, LabCorp discussed its preference for a different approach.

"During the meeting, LabCorp was adamant that they wouldn't build a draw site network in a market before gaining managed care contracts," recalled Bonello. "One reason is that Wall Street investors don't have the patience to see such a growth strategy take shape and deliver growth.

Alternative Points Of Entry

"So, LabCorp's general approach would be to use lower-cost entry strategies. It would create a presence in these new markets by tapping alternative channels," he continued. "These could be drug stores, sites within retail walk-in quick clinics, or ventures involving local healthcare providers or health systems."

Bonello speculated that one urban market likely to be on the LabCorp's expansion list is the New York City

metropolitan area. “Not only does New York City have a large population, but the metro area includes the New Jersey and Connecticut areas that are also quite populous. LabCorp’s existing resource in this market is its laboratory in Raritan, New Jersey.”

Managed Care Trends

Another subject discussed was current trends in managed care contracting for laboratory testing services. “It is LabCorp’s view that the nation’s largest health insurance companies are taking aim at laboratory testing costs, in a serious way that is different from earlier years,” noted Bonello. “Laboratory testing costs were not a major issue until recently. There are a couple of reasons for this.

“First, the amount of money being spent on laboratory testing has increased in recent years,” he observed. “More tests, more utilization, and greater costs all contribute to a higher lab spend. This increase in the cost of laboratory testing has attracted the attention of executives in the largest health insurance corporations.

“Second, most payers have addressed the budget-busting aspects of rising costs in prescription drugs and imaging. That makes increases in lab testing costs the next priority,” added Bonello.

More Spent On Lab Tests

“Third, there has been a significant amount of consolidation in recent years as the largest health insurers increased the number of covered lives by acquiring smaller managed care companies,” he said. “In absolute terms, the aggregate amount of money now spent on laboratory testing in these big insurance companies has become a very large number. When a payer spends \$1 billion per year on lab testing, any reduction in that number represents significant savings.”

LabCorp’s executive team told Bonello that large managed care companies are now more willing to take active steps to control the lab spend. “These include tactics like refusing to pay out-of-network claims (or paying at reduced rates, or sending payment directly to the patient rather than the laboratory), restricting physician’s ‘client billing’ arrangements for lab testing, and even penalizing physicians for continuing to use laboratories that are out of the network,” stated Bonello.

“What is different now is that these big managed care firms are demonstrating a willingness to take difficult and unpopular steps to trim back the amount of money they spend to reimburse for laboratory testing.”

“It was indicated that **WellPoint** and **United Health Group** are examples of two large payers which have become more focused on controlling their spending on laboratory tests,” he added. “Certainly the tactics listed above have been around for many years. What is different now is that these big managed care firms are demonstrating a willingness to take difficult and unpopular steps to trim back the amount of money they spend to reimburse for laboratory testing.”

Returning to the subject of growth and acquisitions, LabCorp’s executive team indicated that they continue to be extremely interested in pursuing acquisitions that would be “science focused.” “LabCorp has a definite interest in acquiring laboratory companies that provide anatomic pathology services,” observed Bonello. “Labs that provide high-end diagnostics and esoteric testing would also be attractive to LabCorp.

“I did not see the same enthusiasm for acquiring companies to gain access to technology or intellectual property,” he added. “My conclusion is that LabCorp wants to concentrate on adding tests to their menu that have clear clinical value, supported by the types of clinical studies that would generate increased acceptance of the new diagnostic technology by clinicians and payers.”

Another topic that will be of particular interest to anatomic pathologists and their group practice administrators is LabCorp’s view that digitization of anatomic pathology (AP) images is likely to be the next trend in the profession. “Certainly the conversation on this point was quite general and centered around several futuristic ‘what ifs’,” recalled Bonello. “What I found fascinating was their speculation on how digitization of AP would stimulate changes in the marketplace.

AP Cases Come to U.S.

“One future scenario that LabCorp discussed was that digitization would make it possible to provide advanced diagnostics from a centralized location,” he continued. “However, the thinking was not that this would lead to the outsourcing of anatomic pathology professional services to countries with lower costs, such as India or China.

“To the contrary, LabCorp could make an argument that digitization would allow physicians across the globe to refer cases to specialized pathology centers in the United States and other developed countries. The goal would be to have world-class pathologist sub-specialists diagnose the cases, since the quality of the outcome would likely be the motivation driving these referrals—not lowering the cost of diagnosis by a few dollars.”

With the major investments LabCorp has made in acquiring

anatomic pathology companies in recent years, there was discussion about the current state of the histology business, both in the United States and at LabCorp. In particular, how did LabCorp view the trend of specialist physicians establishing their own pathology labs and retaining their own pathologists to read the processed slides?

Bringing Histology In-House

“The word LabCorp used to describe this segment of the lab testing market place was ‘tough’,” noted Bonello. “The second quarter earnings statement tells the story. LabCorp reported that histology volumes were flat or slightly less, compared to last year’s second quarter. It acknowledges that competition from physicians, such as urologists and gastroenterologists, who are bringing their histology work in house, was a factor.”

Bonello’s comments presented here are based on a summary of key points he issued to his research clients following his visit to LabCorp headquarters in Burlington. THE DARK REPORT asked him to expand on those points so that readers of THE DARK REPORT could get a sense of the new CEO’s perspectives on the laboratory testing marketplace.

Predictions Made in 2003

LabCorp’s current views of how laboratory medicine may evolve should be reviewed against the remarks made by current CEO Thomas P. Mac Mahon in the interview published in the April 14, 2003 issue of THE DARK REPORT. In the three years since that interview, most of what Mac Mahon predicted for health-care and the laboratory industry has tracked closely with actual events. For that reason, LabCorp’s views on unfolding trends are likely to be well-informed.

TDR

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CEO SUMMARY: *With sustained pressure on laboratories to cut costs, reduce errors, and raise quality, lab managers need faster access to detailed information about lab work processes. One solution is to use middleware to collect data in real time from the LIS and other sources, then analyze it to identify problems and opportunities for improvement. Three laboratories which implemented a middleware real time decision support system credit it for major gains in productivity and quality.*

GUIDES MANAGEMENT DECISIONS

Middleware Produces Data In Real Time for Lab Managers

GROWING NUMBERS of laboratory-managers and pathologists want detailed data in real time to guide management decisions in their laboratories. One way to accomplish this goal is to use middleware solutions designed specifically to support management decisions.

An early pioneer in the use of middleware solutions to support real-time decisions and management of the laboratory is **Pennant Laboratories**, which is part of the **Wyoming Valley Health Care System**, a two-hospital system of 597 beds located in Wilkes-Barre, Pennsylvania. It was back in 1996 that Gerard Clifford, Pennant's

Administrative Director of Laboratories, began using a middleware product called "MAST" to pull data from the laboratory information system (LIS) in real time. MAST then analyzes and presents that information in pre-designed ways that allow lab managers to swiftly identify situations that require intervention or management action.

Key Management Tool

"MAST has become a key management tool for us," stated Clifford. "Once we gained access to detailed information in real time and saw how it allowed us to respond quickly to all sorts of events unfolding within the laboratory, it moti-

vated us to go further with using middleware to extract all types of information about laboratory processes."

MAST is a product of **Management Decision Systems, Inc. (MDSI)**, based in Holden, Massachusetts. It stands for Management, Accountability, Staffing & Service Tracker. "This system is customized by each laboratory client," explained Richard A. Ouellette, MS, MT(ASCP)H, CHE, who is President and CEO of Management Decision Systems. "The client chooses the performance criteria and MAST extracts the necessary data from the LIS and HIS (hospital information system), as needed.

able that it became the alpha development site and birthplace for the ORF Tracker (Occurrence Report Form) system, also an MDSI product. In the years since 1998, Pennant grew from 1.5 million tests per year to over 4.5 million tests and it became a highly automated laboratory.

"MAST is very robust. Other systems don't even come close to what MAST does for us," noted Clifford. "We've looked and haven't found anything with comparable functions and effectiveness.

Response To Service Issues

"MAST feeds its data into dashboard summary reports that are invaluable in responding to service issues for our inpa-

"Once programmed, the system runs itself," noted Ouellette. "It looks at pre-analytical, analytical, and post-analytical trends from an hourly to a monthly basis. It can track work flow that is internal or external to the laboratory department. It enables laboratory staff to focus their time on fixing systemic errors. It also helps them identify opportunities to proactively improve work processes. Trigger Reporting analyzes predefined performance metrics and automatically e-mails the manager about changes & deviations."

Pennant Laboratories found the information produced by MAST to be so valu-

able that it became the alpha development site and birthplace for the ORF Tracker (Occurrence Report Form) system, also an MDSI product. In the years since 1998, Pennant grew from 1.5 million tests per year to over 4.5 million tests and it became a highly automated laboratory.

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"MAST feeds its data into dashboard summary reports that are invaluable in responding to service issues for our inpa-

tients and lab outreach program," he added. "Each day, I can compare our turnaround time and see where problems are occurring. MAST reports allow me to identify an issue and determine a legitimate problem from a rare occurrence. This is especially useful when a physician questions a lapse in the system."

"These detailed reports show exceptions and the point of cause. The supervisor addresses the findings with the technologist or phlebotomist. Together, they work on the problem to identify why it occurred," said Clifford. "We also monitor the number of specimens by the hour to check if we are meeting or exceeding

Useful Real-time Information Supports Active Intervention

MANY LAB MANAGERS have an LIS system that produces reams of data, often with month-end reporting. As a result of delayed reporting, systemic problem-solving is reactive and not proactive. Yet, timeliness in problem solving can be the service edge that beats the competition or improves the laboratory's position with the medical staff.

In the middleware solution designed by Management Decision Systems, Inc. (MDSI), there is no human intervention. "A virtual server does all the work to poll data from the LIS and other sources in real time, then use it to produce performance metrics," said MDSI Founder and CEO, Richard E. Ouellette. "Dashboard graphs show the actual performance, variation, trends, consistency, and target goals. Behind each graph is a daily detailed report that is used by supervisors at the bench level or nursing unit."

"Each supervisor and pathologist is provided a 'real-time' desktop connection to the ORF Tracker program," continued Ouellette. "Laboratory occurrence reports are centrally entered and available immediately. These reports are available online to monitor current status, manage follow-up, trending, and analysis."

our turnaround times and productivity for the entire laboratory.

"Most important for us are the daily and monthly reports of every customer. These include specimen volume, insurance contract information, and dollar value of the account," he stated. "This information allows us to track capitated accounts and associated non-capitated work received from each client. By using MAST to closely monitor this work, we have grown our business in one county by 9%."

MAST and ORF Tracker also help Clifford's laboratory in other ways. "We use the reports to educate senior management and major players as to the value of the outreach business," he commented. "There is continual focus on the lab's inpatient numbers. However, 80% of our work comes from outpatients and outreach. We share specific information with our customers and show them why it is necessary to make policy changes to ensure regulatory compliance. When clients see the documentation and information, they readily agree. This has been a very positive tool to build client loyalty to our laboratory."

There is another useful benefit from real-time data feeds to Clifford's management team. "Our laboratory is ready for unannounced inspections at any time," he observed. "We exceed what is expected, both in the lab and working with other departments."

30 Different Indicators

"CLIA final rule requirements are extensive and quite specific in defining the quality program—more so than CAP or JCAHO," he continued. "To support our quality program, we have 30 different indicators that break down work processes in all sections of the lab. We can look at our errors per 10,000 tests and spot where errors are occurring. We can implement a fix and almost immediately evaluate the change."

MDSI and Ouellette have worked closely with Clifford over the years and made numerous enhancements to the MAST and ORF Tracker reports. Reports are customized to the clients' specific parameters. As enhancements are made for one laboratory client, MDSI will make those same enhancements available to other clients without charge.

Another laboratory using middleware to collect real-time information and

guide management decisions is the laboratory at **Maryland General Hospital** (MGH), a 276-bed facility in Baltimore, Maryland. “MAST is a very powerful tool to monitor our service levels for all of patients,” stated John Braun, M.D., Interim Laboratory Director at MGH. “The MAST dashboard summary is the first thing I look at when I arrive in the lab. It enables me to see the trends of stats and urgents, the stat turnaround time from stat order to receipt, and stat receipt to verified result. In one graphical page, I can see what has happened over the previous 28 days up to the present day. I can spot developing trends from as little as one day’s data.

Detailed Reports

“Before this software solution, we did not have a robust method to capture failures, derive an analysis, and investigate trends,” he added. “Now my supervisors get detailed reports that let them identify and work on the specific outliers for their sections. The detail is granular enough to get down to the level of individual technologists, phlebotomists, and nurses.”

Braun’s lab started using MAST in May 2004, and credits it for substantial gains in operational efficiency and quality, as well as improved turnaround times. Braun explained, “The MAST system is a daily routine. We monitor turnaround time from phlebotomy draw to test completion. We also look at the ordering patterns in the hospital. This allows us to adjust our staffing patterns quickly, so we can maintain our monitors for stats and other service issues. We get a daily understanding of what happens in any section of the lab, with any instrument, and even by individual employee. This enables us to be more proactive in solving issues that affect patient care.”

“Our **Meditech** LIS is not capable of providing this type of report. The

MAST software package provides us with a custom database and analysis tool,” said Braun. “It fits our particular situation for specified indicators which allows us to follow our trends.

“Our quality program is supported by the ORF Tracker system, which allows us to monitor laboratory failures,” he stated. “All failures get ‘ORF’ed,’ as we call it. ORF reports have created a new culture and a new enthusiasm among the laboratory staff. They see that, whenever a plan of action hits my desk, there are immediate steps taken to implement it. We track pre-analytical, analytical and post-analytical issues, down to various sub-categories.”

Inci Hepner, BS, MT(ASCP), the Point of Care and Quality Assurance Supervisor, seconded Dr. Braun, “Both MAST and ORF Tracker systems have made a significant difference in the lab. For example, our turnaround-time has improved greatly. During the first 12 months that the MAST system was used in our laboratory, there was a 167% improvement in a.m. turnaround time, from 30% success to consistently performing at 80% success” stated Hepner. “Staff sees reports on a daily basis and is thus constantly aware of how precisely the lab is meeting its goals.

Dramatic Improvement

“We also used this information to generate dramatic improvement in specimen collection and labeling errors. In the blood bank, use of the ORF Tracker helped us reduce mislabeled errors by 70%,” she continued. “The reports help us provide targeted education sessions internally and external to the lab, as we can easily pin-point where the need lies. We are able to track the problems, implement a fix, and track the change for improvement.

For example, we use these reports with nursing whenever they are

involved in the process,” Hepner explained. “I can resolve issues in seconds instead of days. This makes a big difference in our relationships with the medical staff and nursing.”

“Benefits are seen daily,” added Braun. “We know the specific delay areas, volumes of tests by time and area of the hospital, and errors by person. I can dissect any group of occurrences, from system errors to random people errors. I can track any item, by day, week, or month. My reports to the Quality Improvement Council, the Medical Executive Committee and the Board of Directors are far more efficient, accurate and timely. They have been well received.”

In Use At Swedish Hospital

Nine months ago, 1,200-bed **Swedish Medical Center** of Seattle, Washington began using the MAST system. MAST dashboard reports, using data from the **Antrim** LIS, enable Brian Kuske, Vice President of Ambulatory and Ancillary Services at Swedish, to see lab activities from a 30,000 ft. level, while giving him the confidence that laboratory staff can work on issues at ground level.

“We have a contract with **Laboratory Corporation of America** to provide laboratory services. This middleware solution allows me to work with LabCorp managers to track and measure success and failures in the pre-analytic, analytic and post-analytic phases of lab testing.” Kuske explained. “We decided to implement the MAST system because we wanted more specific and timely information.

“We were concerned that turnaround time standards were not being met,” he said. “We also wanted to develop a full range of consistent measurements made in real time. The goal was to make management and the laboratory more accountable and timely.

“After installation of this middleware and because of data issues with the LIS, it took us about six months to fine tune the reports,” continued Kuske. “Now there is much greater confidence in the data. Dashboard reports are easy to read and timely. They allow us to make strategic decisions and share data with lab staff, nursing units, quality and clinical effectiveness councils, the medical staff, and the various quality committees. We track productivity and turnaround time closely.

“Initially the laboratory staff was a bit anxious about such detailed data and accountability, but overall they are pleased with the accuracy of data, and improvement from the past. One of our goals was to speed up the pre-analytic time from the time of test order to phlebotomy draw and sample time to the lab. MAST report information was used to make changes. These changes were monitored with the reports, allowing us to measure our success in real time, without having to wait one to two months for confirming data.

“In less than nine months we have seen a significant improvement in our 15 performance metrics, including a 40% improvement in test turnaround time,” he added. “We have a 95% success rate for our morning work to be reported by 8:00 a.m. This is business intelligence where and when you need it.

Start-Up Costs

“There is an initial investment for the start-up costs, which include consulting time in deciding on the performance metrics, building the interface, and refining the product,” stated Kuske. “After that, it’s only the subscription cost. There’s better accountability between Swedish and LabCorp. All parties agree on the metrics and work on our successes together.”

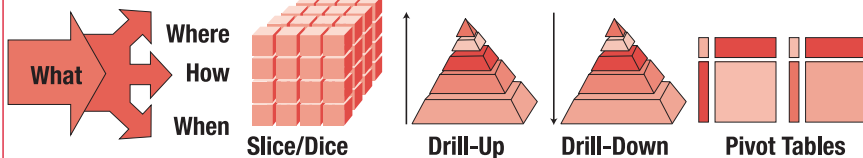
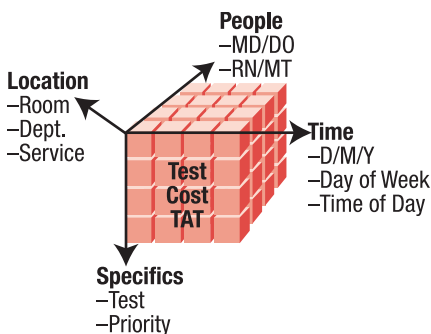
Using Middleware to Guide Real-Time Problem-Solving in All Areas of the Lab

REAL TIME DECISION SUPPORT SYSTEMS SHOULD BE PART OF EVERY LIS. However, available LIS products lag in their ability to supply the laboratory manager with easy solutions. Business intelligence tools are becoming necessary to help labs meet expectations for tighter turnaround time, to improve the timeliness of diagnosis, and to contribute in reducing length of stay. Business intelligence tools also allow hospital lab outreach programs to monitor new and old client activity and assess sales force commissions and productivity.

Data from “Four Dimensions” Guides Lab Decisions

The example at right shows how the middleware solution provided by Management Decision Systems, Inc. (MDSI) builds a database to view the measures of laboratory tests, costs, and turnaround time. This database approach creates multiple dimensions that relate to, and explain, “measure” activities and behaviors. Data is found wherever the dimensions intersect.

Below is a diagram which shows how the OLAP database allows information to be evaluated in a variety of ways.



Laboratories with the business intelligence middleware tools from MDSI are using the systems in these ways:

- Dashboard reports evaluate overall laboratory activity on predetermined performance metrics on a 28-day rolling report, or a high-level daily analysis. Includes the ability to drill down and “slice and dice” the information.
- Captures accurate turn-around-time data in real time for each laboratory. Because every lab is unique, comparison data is useless due to the complexity of steps involved.
- Reports provide better accountability at all levels of the lab.
- Easier to focus on issues at a specific point in the analytical process, make changes, and monitor the results of the implementation.
- Productivity reports educate senior management, determine staffing schedules, and identify areas of need by the hour.
- System tracks specific data needed to meet CLIA guidelines for quality programs.
- Easy to dissect occurrence reports to determine system errors or random people errors, then provide focused education whenever appropriate.
- Tracks outreach clients, along with associated commissions for sales reps.
- Tracks clients involved with capitated accounts and associated non-capitated work.

LabCorp has also decided to bring in ORF Tracker at Swedish to help monitor quality issues. According to Kuske, Lab Corp representatives are impressed with the MAST system and intend to implement it at other laboratory locations.

Decision Support In Labs

THE DARK REPORT observes that the middleware applications now in use by the laboratories of Pennant, Maryland General Hospital, and Swedish Medical Center provide real-world examples of sophisticated decision support in the management of clinical laboratories. Because the middleware solution gathers data in real time, it allows lab managers to spot problems or negative trends almost instantly—and fix them just as quickly.

This middleware enables lab administrators and pathologists to monitor the smallest details in their lab operations in real time. It is consistent with the quality management requirements of Lean, Six Sigma, ISO-9000 and other quality programs. These all require managers and staff to collect accurate and timely data. This data is used to identify problems and opportunities for improvement. The better the data, the better the decision which is based on the data.

Real-Time Monitoring

Use of middleware to enable trouble shooting and process improvement in real time is the future of laboratory operations. The three laboratories profiled here are first-movers and provide powerful evidence that the standard of performance in laboratory management is moving to higher levels.

It is important for laboratory administrators and pathologists to recognize this development. Today's laboratories are under sustained pressure to improve productivity, reduce errors and mistakes, and raise the quality of both lab test results and the service provided to patients, physicians, and payers.

Middleware's Analytical Tool Identifies Multiple Solutions

AT THE HEART of the MAST and ORF Tracker middleware systems is an online analytical processing tool (OLAP), which incorporates a Lazarus Data Pump.

Data is loaded into OLAP in real time from LIS, HIS, or several different database management systems. It then takes as little as five to 20 seconds for the MAST and ORF Tracker systems to produce answers to such questions as "what if we...?"

"OLAP's use of pivot tables enables multidimensional problem solving," explained Richard Ouellette, CEO of Management Decision Systems, Inc. (MDSI). "Lab managers can drill up and down and 'slice and dice' the data in almost unlimited ways. It just takes a click of the mouse. Data and the resulting analysis can be easily formatted and charted for discussion and further action. These OLAP-based tools enable lab managers to evaluate how productivity is changing, model different ways to solve a problem, and see which changes will have the greatest financial benefit to the laboratory."

Simply stated, the healthcare system expects laboratories to deliver more. To meet these higher expectations, laboratory management must become more sophisticated. That is why real time decision support middleware, such as currently used at the laboratories of Pennant, Maryland General Hospital, and Swedish Medical Center, will become widespread.

TDR

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—By June Smart, Ph.D.

Healthcare Strategies

Walk-In Clinics in Retail Stores Is Hot New Healthcare Trend

CVS Pharmacy chain buys MinuteClinic for an estimated price of \$170 million

HERE'S A NEW HEALTHCARE BUSINESS MODEL THAT IS POISED TO transform primary care in the United States and is likely to upset any number of traditional clinical relationships in this country.

The business model is the walk-in, 15-minute clinic located in a retail store. These types of clinics can already be found in stores operated by **Wal-Mart, CVS, Rite Aid, Osco, Sav-on Drugs, Kroger, Shoprite, and Piggly Wiggly.**

The concept was created by **MinuteClinic** of Minneapolis, Minnesota. Its first clinics opened in 2000. MinuteClinic caught THE DARK REPORT'S attention when it opened six clinics in **Target** stores in Baltimore during the summer of 2004.

Since then, the company has opened 83 clinics and 66 of these are located in CVS Pharmacies. On July 23, 2006, CVS disclosed that it was acquiring privately-held Minute Clinic for a purchase price estimated at \$170 million.

Simple Business Plan

The business model is extremely simple. In a space of 200 to 500 square feet, a nurse practitioner (who is under the supervision of an on-call physician) is available to treat patients. The service menu is limited to common conditions that can be diagnosed quickly and

for which prescriptions can be written. Some of these conditions include strep throat, ear infection, pink eye, influenza, and seasonal allergies.

The service goal is to diagnose and treat the patient within 15 minutes. If the nurse practitioner is busy, the patient is given a pager and can shop in the store until paged. Cash payment is encouraged and fees typically range from \$40 to \$80 for most services. The patient can have the prescription filled by the pharmacy located in the store.

Rapid Expansion

Here are several remarkable facts about this rapidly developing healthcare delivery vehicle. First, there are already 12 "rapid clinic" companies with at least 143 clinics now operating in retail stores in various regions of the United States. Second, this business sector is likely to expand quickly. MinuteClinic plans to open more than 150 clinics this year. Competitors **RediClinics** (Houston, Texas) and **Take Care Health Systems** (Conshohocken, Pennsylvania) have announced plans to open 75 and 200 clinics, respectively, during the next 12 months.

Third, integrated healthcare systems are entering the rapid clinic business. These include **Aurora Healthcare** (Milwaukee, Wisconsin), **AtlanticCare Health System** (Atlantic City,

New Jersey), and **Memorial Health System** (South Bend, Indiana). Fourth, one expert in this field has predicted in *The Wall Street Journal* that there could be as many as 10,000 of these clinics in operation by 2010.

Not Yet Profitable

THE DARK REPORT wants to add another remarkable fact. To date, no company operating these rapid clinics has publicly admitted to making a profit. That implies high risk for this business concept.

It also could mean that these companies are following the business strategy adopted by **Amazon.com** back in the 1990s. During those early years of the Internet and e-commerce, Amazon lost huge amounts of money, but told its investors that it needed to spend that money on rapid expansion so it could capture a dominant market share while the competition was weak. In the case of Amazon.com, the company did eventually show profits and has achieved its goal of being a dominant player in its market niche. It remains to be seen whether the business concept of rapid clinics located in retail stores will produce long term profits.

THE DARK REPORT expects this trend will eventually begin to alter patient flow in ways that affect clinical laboratories. Assuming that the long-term financial viability of the rapid clinic business model is established, companies such as Wal-Mart and CVS Pharmacies, with 3,800 and 6,100 stores respectively, have the ability to offer multiple “primary care clinics in most cities.

As more consumers opt to use these types of healthcare facilities for simple ailments, primary care physicians will see fewer patients. That may cause a moderate reduction in the volume of laboratory testing performed by office-based primary care physicians. However, these retail, walk-in clinics

will alter the referral flow of patients—something that is important to most primary care physicians. This threat has already stirred a few healthcare systems to act. In some cases, as noted above, they have established their own rapid clinic operations. In other cases, health systems and physician groups are signing contracts with these rapid clinic companies to provide medical oversight and similar clinical services, in exchange for patient referrals.

At a minimum, laboratory administrators and pathologists should understand that the emergence of this healthcare business model, located in retail outlets, is a response to consumer demand. Who likes to go to the emergency room, or even a busy doctor’s office? It is particularly frustrating for such patients when they already know what is likely to be wrong with them—a minor case of the sniffles, a bladder infection, an earache, or similar. What they seek is speedy confirmation of the obvious and a prescription they can fill quickly that will make them feel better. That is why this 15-minute clinic model, from exam to diagnosis, has proven popular almost everywhere it has been tried.

Lab Tests In Pharmacies?

This is an important trend and THE DARK REPORT will be providing more intelligence on this topic in the coming months. It is significant that these walk-in, 15-minute clinics are generally going into retail stores which also have a pharmacy. Over time, the success of in-store clinics may provide pharmacies with a patient flow that allows them to expand their services to include on-site laboratory testing, x-rays, and more complex clinical treatments.

That is just one reason why the laboratory industry should not underestimate the potential of this new business model to trigger a cascade of changes, some of which may affect clinical labs. **TDRE**

INTELLIGENCE

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



On September 8, **Becton, Dickinson & Company**

(BD) announced that it would acquire **TriPath Imaging, Inc.** for a purchase price of approximately \$350 million. TriPath's share price has not moved significantly over the past five years, so many shareholders were pushing for change. BD and TriPath have been close collaborators in several areas of molecular technology development.

CYTYC BIDS FOR VISION

There was an interesting cat-fight between **Ventana Medical Systems, Inc.** and **Cytec Corporation**. In August, Ventana and **Vision Systems Ltd.** of Sidney, Australia, entered into a friendly agreement. Ventana would pay about US\$346 million to buy the manufacturer of instruments and reagents used in diagnosing cancer. On September 18, Cytec announced a tender offer to acquire Vision Systems, at a price of about US\$374 million. Ventana ceded the sale of Vision Systems to Cytec, but has filed a patent infringement suit against Vision Systems.

FDA ISSUES GUIDANCE ON MOLECULAR TEST APPROVALS

Earlier this month, the **Food and Drug Administration (FDA)** issued a document that is the first step to assert a role for the agency in regulating "*in vitro* diagnostic multivariate index assays" (IVDMIAAs). On September 7, the FDA posted "Draft Guidance for Industry, Clinical Laboratories, and FDA Staff—*In Vitro* Diagnostic Multivariate Index Assays" on its Web site. (<http://www.fda.gov/cdrh/oivd/guidance/1610.html>). The FDA has been communicating with **Genomic Health, Inc.** of Redwood City, California. Genomic Health's Oncotype DX is a multivariate, algorithm-based-assay. It began marketing the assay in 2005, without filing for pre-market review.

ADD TO: FDA Actions

Experts consider the FDA's release of the draft guidance to be a sign that the agency wants to issue more definitive regulations that will address assays that incorporate MIAs. It is already developing guidance that

affects ASRs (analyte specific reagents). In the draft guidance, the FDA says an IVDMIA tests is a device under section 201(h) of the Federal Food, Drug, and Cosmetic Act. Posting of the draft guidance starts a 90-day comment period. Lab industry groups are studying the new draft guidance and preparing a response.

For the first time, the **Florida Health Care Coalition**, (FHCC) has released its annual survey of HMO quality to the public. This year's survey, which included six HMOs, showed that none of them were consistently matching national benchmarks for quality. FHCC represents many of Florida's large employers on healthcare issues. Eight measurements of plan quality were surveyed. The highest-scoring national plan had a score of 95%. The top score for any of the Florida HMOs was **Cigna**, at 79%. The other scores were: **Aetna**–76%, **Blue Cross and Blue Shield of Florida** (BCBSF)–69%, **United Healthcare**–61%, **Humana**–59% and **Vista**–22%.

*That's all the insider intelligence for this report.
 Look for the next briefing on Monday, October 16, 2006.*

THE **D**ARK REPORT

UPCOMING...

- **Transparency in Prices and Quality: Why Pathologists and Labs Need to Prepare.**
- **What's Working in Pathologist Recruiting and Competitive Compensation Packages.**
- **Point-of-Care Testing Used to Lower Core Lab Costs and Raise Healthcare Outcomes.**



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