

From the Desk of R. Lewis Dark...

THE **RD**ARK **REPORT**

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

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Commentary & Opinion by...

R. Lewis Dark

Founder & Publisher



Using Laboratory Informatics to Add Value

IN THIS ISSUE, YOU WILL READ ABOUT THE SALE of **Spectrum Laboratory Network** and the ongoing integration of laboratory services at **Geisinger Health System**. Although, on first reading, it may seem that these two stories are unrelated, I would like to call your attention to a common attribute that underpins the success of these two laboratory organizations.

Both Spectrum and Geisinger's laboratory division share a business strategy of using sophisticated information technology to support the clinical needs of the physicians they serve. In the case of Spectrum, the laboratory company offers office-based physicians an increasingly-sophisticated informatics platform for lab test ordering and results reporting. It continually adds functionality to this system and supports an expensive field force of IT installers and field service reps. When Spectrum gains a new client account, it typically takes only 48 hours for this service team to install the system and have the office staff trained.

At Geisinger, the situation is different, since it is a self-contained integrated delivery network (IDN) and owns hospitals, clinics, and other facilities. To serve this environment, Geisinger's laboratory division has proactively worked to drive operational and informatics integration to a deep level. As you will read on pages 9-14, it is that ability to capture point-of-care test (POCT) results from any part of the Geisinger system that makes it world-class in this attribute.

In both lab organizations, the strategy of deploying sophisticated informatics to support the clinical needs of physicians is paying off. At Spectrum, its revenue growth for outreach testing has averaged a compound rate of 27% over the past four years. At Geisinger, the laboratory uses its informatics capabilities to support important initiatives in physician pay-for-performance, to support adherence to clinical practice guidelines, and to provide an information-rich lab test data base to help advance Geisinger's efforts in the field of evidence-based medicine.

The sustained successes of both laboratory organizations in their respective markets validates a longstanding prediction we've been making on these pages: in healthcare's next cycle of evolution, the lab industry's winners will be those laboratories which offer sophisticated information services to clinicians.

Spectrum Lab Network Is Sold to Equity Investor

One of three original health system owners continues to hold equity in new company

CEO SUMMARY: *Timing of the sale of Spectrum Laboratory Network to Apax Partners, L.P. was unexpected, but it's been known for some time that the fast-growing regional laboratory was entertaining purchase offers. Under new ownership and with ready access to ample capital, Spectrum is optimistic that it can sustain its rapid rate of growth while maintaining above-average profit margins.*

SPECTRUM LABORATORY NETWORK of Greensboro, North Carolina, was sold last week to **Apax Partners, L.P.** of New York City. Details of the sale were not disclosed.

The transaction was announced on November 7. One motive for the sale to Apax was to cash out the ownership interest of **High Point Regional Health System**. This is the second time in 24 months that a hospital owner of the fast-growing regional laboratory company has decided to convert its equity position into cash.

Apax Partners is now the majority owner of Spectrum Holdings, Inc., which holds the company's assets. As part of the deal, **Moses Cone Health System** retains "a significant ownership position in the

company." Moses Cone is one of the three original health system owners which founded Spectrum Laboratory Network in 1997. **Novant Health System** sold its interest in Spectrum at the end of 2003.

There will be few significant changes in the day-to-day operations of Spectrum as a result of this sale. "We will continue to manage the laboratories of 10 acute care hospitals and maintain our existing sales and marketing program," stated Nate Headley, CEO of Spectrum. "Existing staff will continue as employees of Spectrum. We expect it to be 'business as usual' under our new owner."

Headley attributes Spectrum's current size (annual sales estimated to be \$124 million in fiscal year 2005) and

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rapid growth as the major reason for the decision by High Point and Moses Cone to sell Spectrum Laboratory Network. “Our health system owners have evolved in their thinking about this laboratory organization in recent years,” said Headley. “Back in 2000, about the time I arrived, the three owners didn’t fully anticipate the potential of this laboratory to become a significant and viable competitor in the out-reach marketplace.

Sustained, Rapid Growth

“Spectrum has grown rapidly in recent years,” he continued. “Since 2000, Spectrum has posted an annual revenue growth rate of 27% compounded. EBITDA (earnings before interest, taxes, depreciation, and amortization) has increased 54% per year during the same period. (*See TDR, March 7, 2005.*)

“The mindset of the health system owners changed as they watched their original investment grow rapidly. “Of course, their primary business is to provide inpatient and outpatient services through hospitals and related facilities,” he noted. “To maintain strategic focus on this mission, each of the original three partners, in their own timing, decided to convert their equity to cash and put this capital to work elsewhere in their health system.

Partners Opt For Cash

“Novant was first to reach this decision. In late 2003, they converted their equity into cash and left the partnership,” recalled Headley. “High Point and Moses Cone made the same decision earlier this year. High Point has immediate plans to use the proceeds from this sale elsewhere in its health system. Moses Cone has rolled a portion of its equity into the new holding company. Going forward, it will continue to be an investor in Spectrum.”

One factor that encouraged Spectrum’s health system owners to sell their laboratory at this time was a plentitude of buyers. During the past two years, a steady stream of interested buyers has approached Spectrum’s owners with strong offers to purchase the laboratory.

“These buyers fell into two categories,” said Headley. “There were a number of strategic buyers, like public lab companies, already active in healthcare and for which Spectrum’s laboratory testing business would complement their existing business activities.

“Private equity firms were the other category of buyer that approached us,” he continued. “These companies are looking for good investments. They want to acquire a laboratory, retain the existing organization and utilize it as a platform for further growth.”

Lots Of Buyer Interest

According to Headley, the parade of potential buyers was ever-growing. “We were contacted by a significant number of private equity companies,” he noted. “Our owners preferred this category of buyer over the strategic buyer for several reasons.

“The primary reason was to maintain continuity in both the management philosophy and operational team that manages the 10 acute care hospital laboratories of our former owners,” said Headley. “The private equity buyer generally wants the company to maintain all its existing operations without significant change, which is what our owners also want.

“Next, our owners wanted the new buyer to be able to provide capital whenever needed to fund additional growth. In fact, after the sale, Spectrum will hold a modest capital

reserve and Apax has stated its willingness to fund acquisitions that we believe will be synergistic with Spectrum's operations," he observed.

No Acquisition Plans

Headley was quick to add that Spectrum has no specific plans to acquire laboratories. But he did note that the purchase of **MedEx Laboratories** in late 2003 had been highly successful. "MedEx contributed significantly to our growth and enhanced our operating margins," he stated. "In fact, we currently add two new clients per day across our five-state service region. If we were to acquire another laboratory, it would need to be one that complements the momentum we already have in the marketplace."

Spectrum is glad to have an owner with plenty of capital. "Competition in our region is intense," observed Headley. "We continue to add market share, and we attribute much of this to the investments we have made in information technologies. Currently we have 725 client sites that are electronically-linked to our laboratory.

Uses of Laboratory IT

"In many ways, these electronic bridges to our physician-clients have allowed us to offer enriched services and do a better job on the basics, from getting the original test requisition right the first time to delivering test results in near-real time, in a manner which allows the physician to access those results via the Internet.

"That is one of our corporate strengths and it made us attractive to many buyers," he continued. "But we know that competing labs are spending lots of dollars to develop services and new capabilities in informatics. So that keeps us continually looking for new ways to add value and retain Spectrum's competitive edge."

Apax Partners Is Familiar With Clinical Lab Business

APAX PARTNERS, L.P. IS NO STRANGER to the clinical laboratory business. Its acquisition of Spectrum Laboratory Network is the private equity firm's third investment in a clinical laboratory company.

In 1998, Apax invested in Irvine, California-based **US Labs, Inc.** prior to its acquisition last year by **Laboratory Corporation of America**. Apax also made investments in **Prometheus Laboratories, Inc.**, located in San Diego, California in 1999. Prometheus is a company founded to offer both diagnostic and therapeutic services to gastroenterologists.

Founded in 1969, Apax Partners has taken part in the startup of companies such as **Apple Computer** and **Office Depot**. The company manages investment funds totaling approximately \$12 billion. Its investment window is three to seven years. Typically the firm invests between \$5 million and \$100 million in a single company.

Laboratory executives and pathologists will want to track the ongoing progress of Spectrum Laboratory Network under its new owners. Founded in 1998 as a shared laboratory organization by three major health systems in North Carolina, its financial performance and success in the outreach market provide a powerful example to other hospital outreach programs.

From a modest outreach revenue base of \$22 million per year in the late 1990s, Spectrum Laboratory Network is on track to post revenues of \$137 million in 2006. Spectrum demonstrates that hospital laboratory outreach programs do have unlimited potential for growth and profits.

TDR

Contact Nate Headley at
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Private Equity Firms: Ready to Buy More Labs?

*Acquisition of Spectrum by Apax Partners
is sign of heightened investor interest*

CEO SUMMARY: *Times are good in the laboratory industry. At least that's the opinion of a growing number of professional investors. They are searching throughout the country for laboratories to acquire. They are motivated by the consistent financial performance of many lab companies, both public and private. Another message from the Spectrum sale is that hospital laboratory outreach programs have great potential.*

NEWSTHAT A PRIVATE EQUITY FIRM is about to acquire **Spectrum Laboratory Network** can be taken as a sign of heightened interest by professional investors in the lab testing marketplace.

Over the past 10 years, a handful of laboratory companies have enjoyed substantial financial success—even as the overall financial environment for laboratory testing was acknowledged to be dismal for most of the lab industry. In many cases, private equity investment firms were the original source of capital for these laboratory companies during both start-up and early growth years.

Similar Lab Acquisitions

From that perspective, the purchase of Spectrum Laboratory Network, in Greensboro, North Carolina, by **Apax Partners, L.P.** is just the latest of these types of deals. It provides an opportunity to gauge ongoing investor interest in purchasing other laboratory companies.

In the case of Spectrum's sale to Apax, neither the price paid nor the

equity shares owned by Apax and the remaining health system owner were disclosed. However, in the sidebar on the facing page, Chris Jahnle, Managing Director of **Haverford Healthcare Advisors** in Paoli, Pennsylvania, provides assumptions that indicate Apax may have paid as little as \$100 million and as much as \$200 million for a majority stake in Spectrum of between 60% and 80%.

What THE DARK REPORT considers significant is the statement by Spectrum CEO Nate Headley that his lab company had been contacted by a "significant number of private equity companies" expressing serious interest in acquiring Spectrum Laboratory Network. (See pages 2-4.) Pathologists and laboratory directors should recognize that a huge pool of investment money is continuously scanning the laboratory testing marketplace for attractive lab companies to buy.

However, since most private equity firms are looking for a laboratory company doing a minimum of \$50 million in annual sales, this eliminates the

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Haverford Healthcare Advisors Dissects Sale of Spectrum Lab Network to Apax

HOW MUCH DID APAX PARTNERS, L.P. PAY to acquire Spectrum Laboratory Network? The answer to this question is important for hospitals that operate laboratory outreach programs. That's because the price paid for Spectrum's outreach testing business provides a useful benchmark for the capitalized value of other hospital-based laboratory outreach programs.

Since specific details about the Apax/Spectrum acquisition were not made public, THE DARK REPORT turned to **Haverford Healthcare Advisors** of Paoli, Pennsylvania for insight and comment. Over the past two decades, the principals of Haverford have played a role in a significant number of sales involving laboratories and pathology group practices.

Sales Assumptions

"Based on indicated guidelines for valuing a clinical laboratory, we can develop a reasonable range for the probable price that Apax paid to acquire Spectrum," stated Chris Jahnle, Managing Director at Haverford. "Assume that Spectrum had annual revenues of \$125 million in 2004. Also assume that Spectrum's cash flow, as measured by EBITDA (earnings before interest, taxes, depreciation and amortization) is in the range of 15% to 20%.

"In recent years, we've seen buyers pay a price that is about nine to 10 times EBITDA for large lab companies, those with revenues of more than \$100 million," explained Jahnle. "Given the assumptions listed above for Spectrum, that would indicate a sales price as low as about \$170 million and as high as \$250 million.

"Further, based upon press releases, we do know that Apax purchased a majority interest and that **Moses Cone Health System** holds the remaining equity," he continued. "If Apax acquired between 60% and 80% of Spectrum, that would indicate that it paid between a low of \$100 million and a high of \$200 million to Spectrum's

owners, using the same assumptions I've already mentioned."

Jahnle uses the market capitalization of lab companies like **Quest Diagnostics Incorporated** and **Laboratory Corporation of America** to verify these value assumptions. "Based on recent share prices for these companies, they are valued at between nine and 12 times EBITDA. One reason for this high multiple is the market's perception that these companies will continue to grow and be successful," noted Jahnle.

"The next smaller group of lab companies with significant revenue and similar to Spectrum, have in recent years been sold at prices based on a multiple of nine or 10 times EBITDA," observed Jahnle. "That generates a sales price that often approaches two times annual revenues."

"By contrast, the prices paid for smaller lab companies are often based on multiples that range from four to six times EBITDA. This generates a sales price that typically ranges from .06 to 1.2 times annual revenue," he added.

"There is another variable which must be considered," he continued. "Spectrum performs a considerable amount of hospital inpatient testing for 10 hospitals, including those of its owner, Moses Cone. In many cases like this, the hospital pays the laboratory on the basis of its historical cost. The ongoing pricing arrangement for lab services between a hospital system owner and the laboratory obviously affects the profit margins of the lab and can reduce or increase the value of the laboratory to a buyer.

"In such cases, we've seen a hospital owner agree to a higher-price, multi-year contract for inpatient lab testing as a way to support a higher sales price for the laboratory," explained Jahnle. "Terms of the laboratory services agreement between Spectrum and its hospital system clients are not known. But that is a variable which could considerably raise or lower the price ultimately paid by the buyer."

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majority of hospital-owned clinical laboratory firms. Spectrum is different because its executive team aggressively used sales and marketing techniques to lift its annual revenue well past \$100 million. That is why it became an attractive acquisition candidate for these types of professional investors.

Profit-Focused Company

Going forward, pathologists and laboratory managers should understand that Spectrum Laboratory Network is no longer an example of a collaborative, shared laboratory services organization owned by multiple health systems. Once it is sold to Apax Partners, Spectrum Laboratory Network becomes a stand-alone, for-profit corporation that happens to hold laboratory management contracts with 10 hospitals.

Following the change of ownership, Spectrum can be expected to act more like a profit-minded commercial laboratory company than a hospital-owned laboratory organization which reflects the values and clinical mission of its parent (often not-for-profit) hospital. However, this takes nothing away from Spectrum's spectacular growth in recent years, which shows the full potential of a well-run, hospital laboratory outreach program to grow profitably and to contribute significant profits to its parent health system or hospital.

Spectrum's Fate Is Known

It should also be remembered that the ultimate fate of Spectrum Laboratory Network has been determined, once it is owned by Apax Partners. Apax is investing capital that comes from several investment funds it manages. Apax Partners states that its investment window is three to seven years.

That means, as early as 2008, but more likely after 2010, Spectrum Laboratory Network will either be

packaged for an initial public stock offering (IPO) or shopped for sale to another buyer. That's because Apax will need to convert its investment in Spectrum so it has enough cash to pay off and close the investment funds it tapped to buy Spectrum this year.

The lab industry is familiar with the parade of laboratory companies funded in this manner, and then later sold so that the equity investment firm could realize profits and pay off their investors. This was the fate of **Unilab**, **American Medical Laboratories**, **Dynacare**, **US LABS**, **Clinical Pathology Laboratories**, **PathLabs** (in New Hampshire), and **Esoterix**, to name a few. It is the probable fate of **AmeriPath** and its new business unit, **Specialty Laboratories**, since AmeriPath's primary shareholder is a private equity firm.

Financial Benefits

For hospital laboratory administrators and pathologists now operating laboratory outreach programs in their community, the main message from the Spectrum sale should not be overlooked. Because its executive team built a profitable outreach business, Spectrum's health system owners were able to realize tens of millions of dollars from their original investment, in 1998, that created the shared services laboratory organization.

This money is now available to Spectrum's parent health systems. It will be used to expand and enhance the ability of these institutions to provide necessary medical services in their community. Lab directors and pathologists should find inspiration in Spectrum's success at building outreach revenues and profits. It shows that hospital laboratory outreach programs can be competitive—if they are professionally managed. **TDR**

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Regulatory Update

Congressional Bill Introduced On Cytology Proficiency Testing

Proposed legislation would enact one-year suspension of current cytology PT program

THERE'S A NEW CHALLENGE to the near-monopoly on cytology proficiency testing held by **Midwest Institute of Medical Education (MIME)** of Indianapolis, Indiana.

Last Friday, the **College of American Pathologists (CAP)** announced a new bill in the House of Representatives that would suspend and revise the existing federal program under which pathologists, cytotechnologists and other professionals involved in Pap testing must be evaluated. Under regulations announced during the past 18 months, during 2005, MIME is the only national provider of cytology proficiency testing (PT) and the State of Maryland's cytology PT program can be used by residents of that state. CAP's cytology PT program has federal approval for use in 2006.

Bill Has Three Co-Sponsors

The bill is H.R. 4268 and was introduced by Rep. Nathan Deal, a Republican from Georgia who chairs the house sub-committee with jurisdiction over this proficiency testing program. Other original co-sponsors are Reps. Sue Myrick, R-NC and Tom Price, R-CA. Titled "The Proficiency Testing Improvement Act of 2005," the bill calls for a suspension of cytology PT testing for a one-year period.

The bill also does not allow cytology PT testing to resume until "the Secretary of Health and Human Ser-

vices makes changes advocated by CAP and nearly 60 other national and state pathology societies."

When the **Centers for Medicare and Medicaid Services (CMS)** announced, late in 2004, that cytology proficiency testing would be required in 2005 and that there would be only one nationwide provider of such PT testing, the outcry by the cytology profession was immediate and loud.

Criticisms Of The Program

Critics of the program note that, since the original rules governing cytology proficiency testing had been issued in 1992, advances in science, diagnostic technology, and medical knowledge have rendered these rules ineffective in meeting their objective of protecting patient health. They argue that, for these reasons alone, cytology PT testing should be deferred until updated and appropriate guidelines can be instituted.

Another firestorm of controversy was the decision by CMS, not only to authorize one national provider for the cytology PT program, but to select Midwest Institute of Medical Education as that sole source. This has caused many cytology professionals to question how and why CMS made these decisions, and whether undue influence played a role in CMS's decision to authorize only one nationwide provider, and give that opportunity to MIME.

CEO SUMMARY: *There's been two benefits from the use of sophisticated laboratory informatics at the laboratory division of Geisinger Health System in Danville, Pennsylvania. Benefit one is a standardized, fully-integrated lab information system that collects all lab test results, including point-of-care, into a single data repository that feeds Geisinger's electronic medical record. The second benefit is how this enriched lab informatics capability is supporting Geisinger's new bio-repository.*

ADVANCED LAB INFORMATICS THAT SUPPORT CLINICAL GOALS

Lab Integration At Geisinger Contributes to Better Outcomes

AS PRESSURE MOUNTS TO CREATE an integrated national health information system, so does the threat for laboratory managers and pathologists who fail to initiate a proactive information technology strategy in their laboratory organization.

One early-adopter laboratory has taken innovative steps to achieve comprehensive information integration on a hefty scale, well ahead of most providers in the United States. Utilizing wide area networks (WANs), Lean informatics, and Medicare's first Physician Pay-for-Performance financial incentive, the laboratory at Danville, PA-based **Geisinger**

Health System (GHS) has achieved two unique goals. First, it played a significant role in helping introduce evidence-based medicine into clinical practice throughout Geisinger's regional health network. Second, the laboratory has created a sophisticated and integrated laboratory test data base that now plays a key role in Geisinger's efforts to create a regional "bio-repository."

Role Of Informatics

"When I think of our healthcare enterprise, I don't think so much of bricks and mortar and hospital beds," stated Jay B. Jones, Ph.D., Director, Chemistry and Health Group Labs at Geisinger. "I

think of statistics running through our information system. This is the essence of today's laboratory.

"Laboratorians and pathologists have to get out of the factory mindset of primarily producing numbers and verifying them to the lab computer," he continued. "This shift in mindset is necessary if the lab industry is to position itself as a proactive asset in meeting the healthcare challenges that face us all."

It is not a coincidence that the Geisinger laboratory is capable of supporting the advanced clinical initiatives at this fully-integrated health delivery network. For the past 15 years the laboratory

has worked steadily to integrate several dimensions of its lab testing services.

First came consolidation of laboratory operations. Next was an upgrade to the information system that formed the backbone of the laboratory data repository. This was followed by a deliberate effort to follow point-of-care testing wherever it was performed within the Geisinger Health System, to electronically capture all POC test results, and to maintain a data base of test results that represented a complete record for each Geisinger patient.

"We have 55 decentralized, owned practice sites with salaried physicians

handling 1.5 million outpatient visits per year," observed Jones. "Our wide area network (WAN) has over 10,000 devices attached to it, including printers, POC connectivity devices, and EPIC. We have EPIC—our electronic medical record (EMR) system—in every examination room and nursing station. This was part of our strategy of full integration. We recognized that we could not take a fragmented approach.

"GHS captures data from laboratory, radiology, pharmacy, and other departments and uses a **DataGate** feeder system to get that information into the EMR," he noted. "We port lab results via internet browser to patients and similarly use an EMR Link for

referring physicians. Twenty different applications run on the lab's client servers alone. Our client server version of EP Evaluator helps us to maintain methods standardization with minimized maintenance.

"Integrating point-of-care testing (POCT) into the informatics mainstream was a critical component," he noted. "Earlier this year, we introduced a thick client work station program at both of our medical centers. The various POC devices—glucose meters, I-STATs—are multiplexed within these work stations.

"Anticipating the future of POC testing, we're already developing the structure to electronically capture POCT infor-

Bio-Repository Project For Mining Health Data

Ongoing INTEGRATION OF INFORMATICS and clinical services at Geisinger Health System has created an information-rich environment. To capitalize on this resource, Geisinger has created the **Center for Health Research and Rural Advocacy (CHRR)** as a resource to further its efforts to boost healthcare quality.

It is a stand-alone facility focused on outcomes. CHRR enables researchers at Geisinger to mine the health system's information-rich data bases in support of research projects to identify genetic links to disease, along with analysis of health outcomes. "The Center is organized around two missions," stated Jay Jones, Ph.D., Director, Chemistry and Health Group Labs at Geisinger. "One is to validate cost-effective means of improving and protecting health for our population and the other is to discover new diagnostic tests. A bio-repository is linked to this effort.

"This is envisioned to be a three-step process," he continued. "First, we would focus on identifying the problems that substantially impact our region. Second, we would produce evidence-based algorithms. Third, we would measure clinical and financial outcomes. Our overall goal would be to produce 'best practices' for defined disease states, then implement these guidelines throughout the Geisinger network with as little disruptive impact on our operations as possible.

"The process would involve seven steps: 1) embed best practices into EMR; 2) get a clinical champion to pilot the new best practice; 3) pilot the new best practice at a site; 4) refine the best practice; 5) get feedback from providers; 6) identify and tweak any problems; and, 7) template out the new best practice throughout the other parts of the network," said Jones.

"Laboratorians will recognize this is the fulfillment of many predictions over the years," noted Jones. "Medical informatics is amalgamating into a statistical science for doing the right tests at the right time for the right reasons—evidence-based medicine. What we are talking about is an emerging era of lab information management."

mation. In a standardized way, it flows through our informatics, first into our LIS and then into the enterprise EMR," added Jones. "The leverage potential for these products is enormous if you can integrate them into the LIS/EMR. We use a **TelCor** connectivity package. **MAS Technology** has a similar product."

All of these strategic initiatives in the laboratory are designed to complement and support Geisinger's master vision for the evolution of healthcare services. This includes the introduction of evidenced-based medicine and the goal of encouraging all clinicians to closely follow clinical guidelines. In fact, Geisinger Health System is one of only 10 sites around the United States participating in the Medicare Physician Pay-for-Performance demonstration program. (*See TDR, February 14, 2005.*)

"As part of the **Centers for Medicare and Medicaid Services' (CMS) Physician Pay-for-Performance Pilot Program**—with improving care and reducing costs as our overall goals—our first objective was to standardize practice throughout the system," explained Jones. "To support this, the laboratory also needed to standardize many aspects of its operations.

Three Clinical Strategies

"At the system-wide level," explained Jones, "Geisinger's three-fold strategy includes: 1) developing best practice guidelines based on evidence from our EMR/LIS archive; 2) replicating these best practices throughout the system; and 3) embedding best practice algorithms into our EMR. The embedding strategy allows us to monitor improvement and healthcare outcomes.

"Within the laboratory, it is an evolving process to support these goals. There are a number of tactical drivers. We have realized significant

savings with Lean Materials Management and by using a single GPO (Group Purchasing Organization),” added Jones.

“It is essential to choose standardized technology across our laboratory system. For this reason we stick with one vendor. We use the **Roche** Modular, E170 with 917s and 2010s at our two medical centers and smaller Integras at our five decentralized practice sites. These are harmonized in terms of reagent platform, LIS test codes, quality control, etc. We also use Lean to minimize the number of standardized test codes in the LIS, further reducing complexity and gaining consistency for our clinicians,” he said.

Preventative Healthcare

“At Geisinger, the move toward preventative healthcare is ultimately driving everything we do,” said Jones. “Within the laboratory, we developed a Lean structure to support this strategic goal. Since we have control over all facilities that collect specimens, we were able to gain efficiencies in pre-analytical work processes. We’ve also standardized labeling and specimen prep across all facilities.”

One exciting development at Geisinger is the initiative to form a bio-repository. Geisinger’s CEO recognized that many of the pieces needed to create a bio-repository already existed within the Geisinger system. One of the most important components already in existence was a lab test data repository that contained the full lab test result records for Geisinger patients, stretching back eight years.

Jones is enthusiastic about the potential of Geisinger’s bio-repository to trigger advances in medical care. The bio-repository is in the first phases of studying several diseases. One role for the laboratory is to collect DNA specimens in support of these

studies as patients involved in the study show up for regular blood draws.

“In today’s informatics-based laboratory, delivering results is just the first step,” stated Jones. “To produce evidence-based outcome information, we have to think about archiving information, rather than just delivering it.

“There are two reasons for this. One is to enable the use of future innovations in diagnostics and therapeutics for the individual patient. Second is to enable the aggregation of data for public health and research purposes,” he explained. “For example, data and bio-repositories are important to enable correlating candidate genes to be analyzed by microarray. We can then make genomic associations to information in the electronic medical record.”

Geisinger leveraged logistics and its pre-analytical system informatics to capture residual specimens for DNA extraction analysis. Geisinger also recognized and leveraged another asset.

“We have a very stable population in rural Central Pennsylvania,” observed Jones. “We have a very rich eight years of deep electronic medical record data archived from our EPIC care system. We have a lot of archived outpatient information. Our CEO, Glenn Steele Jr., M.D., Ph.D., recognized the value of combining these assets to establish a disease-specific, regional bio-repository.

Lab Is Collecting DNA

“Our laboratory supported an initiative to collect and store DNA samples for analysis in conjunction with associated electronic medical data from the LIS/EMR. We throw away 3,000 specimens each day. Now we capture certain ones for storage and DNA extraction.

“It’s important to think about the value of the biomaterial which flows through your healthcare system and laboratory,” he added. “We are now

able to archive genomics and phenotype data. So Geisinger's bio-repository is more than a simple DNA bank.

"One challenge has been the consenting process and guarding patients' HIPAA rights," noted Jones. "We've learned that having phlebotomy do the consenting is not efficient because they don't have time. We're still working on this. One positive factor is that the actual data mining process is simple. We've had M.T.s and M.T. students performing that function.

"Part of the incentive for investing in the bio-repository is a recognition of what payers, employers, and consumers will want in the future: healthcare that focuses on prevention," said Jones. "Efforts to organize and align our clinical services with this goal have been corollary benefits of the Medicare pay-for-performance pilot initiative. It has also spurred further integration of our IT systems throughout the Geisinger Health System."

In Healthcare's Forefront

THE DARK REPORT believes that the laboratory division at Geisinger Health Systems may be one of the most fully-integrated, multi-site laboratory organizations now operating in the United States. Its ability to provide standardized testing across the continuum of care, from hospital inpatient services to rural clinics, to electronically capture, in real time, all test results, including POCT, and to feed this data into an enterprise-wide electronic medical record, puts it in healthcare's forefront.

From one perspective, this is operational integration—a goal pursued by many laboratories serving integrated delivery networks. But at Geisinger Health System, laboratory integration has been directed toward other goals. The most important is to enable clinicians to improve outcomes. One element of this initiative is the need to

standardize clinical practices around accepted guidelines and treatment algorithms. The deep integration of laboratory services at Geisinger becomes an important tool in supporting this clinical objective.

Evidence-Based Medicine

The laboratory is justifiably proud of this accomplishment. It is the future of healthcare and laboratorians at Geisinger are direct contributors. "The broad application of informatics-supported, evidence-based medicine remains theoretical at the national level," commented Jones. "We've actually put it into practice throughout an extensive integrated health system."

Geisinger's other primary objective—to further the practice of evidence-based medicine—depends significantly on the contribution of laboratory medicine. Pathologists and laboratory managers may want to pay closer attention to the work unfolding at Geisinger's Center for Health Research and Rural Advocacy (CHRR), including its recently-organized bio-repository.

It is an early example of how cumulative and complete laboratory test data, compiled from a stable population over eight years, combined with the laboratory's role in collecting DNA specimens to create a DNA bank, underpins research into the causes of disease and potential cures. CHRR has already launched bio-repository research into osteoporosis, obesity, and schizophrenia.

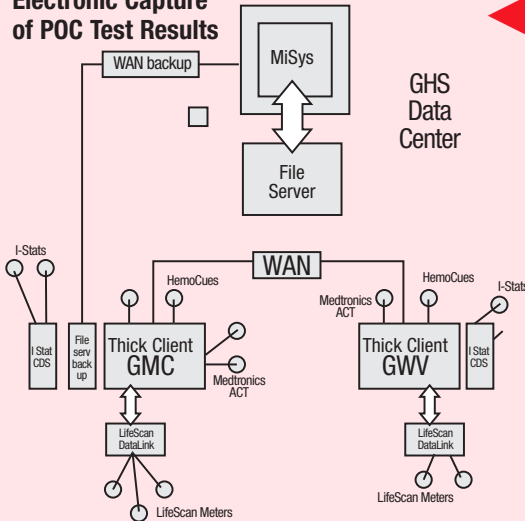
Given its history as an early-adopter laboratory organization for more than 15 years, THE DARK REPORT predicts that Geisinger's laboratory division will continue to be a leader in the laboratory industry. **TDRE**

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—by Pamela Scherer McLeod

Electronic Collection and Integration of Data Helps Geisinger Lab Support Outcomes

Electronic Capture of POC Test Results



AT LEFT IS A FLOW CHART which shows how the laboratory at Geisinger Health Systems electronically captures lab test data, including point-of-care test results, from all hospitals and locations within the enterprise.

The objective has always been to maintain a complete, standardized record of patient results within the LIS. This data then flows into Geisinger's electronic medical record. Currently there are eight years of lab test results on Geisinger patients available for both clinical and research purposes.

Geisinger Takes First Steps to Create a Bio-repository

GEISINGER HEALTH SYSTEMS is among the first in the United States to create a regional bio-repository. A key factor in the decision to proceed was the detailed record of patient lab test results maintained by Geisinger's laboratory division. Such lab test information is a critical component in studies to identify the cause of disease and develop guidelines consistent with the principles of evidence-based medicine.

Regional Bio-repository Pilot Projects

- Osteoporosis (1,000 patients in disease management program, e.g. EMR, bone mineral density DEXA measurements)
- Obesity (several hundred patients biopsied for Non Alcoholic Steatohepatitis, NASH)
- Schizophrenia (patient database; pharmacogenomics)
- Primary care site DNA banking (proposed)

Lab's Ten Contributions to Building a Regional Bio-repository

- 1) Standardized Lab Parameters - archived and extractable
- 2) Well-defined and focused disease management programs
- 3) A broad and deep EMR – archived and extractable
- 4) Standardized (and automated) specimen procurement and banking
- 5) Standardized (and automated) extraction for DNA/expression analysis
- 6) Standardized (and automated) microarray discovery analysis
- 7) A data repository to aggregate and analyze the information
- 8) Patient list from research project (triggers procurement of designated specimen number in LIS)
- 9) Specimen (lavender tube) placed in bio-repository rack by "tube tracker" after testing and before discard
- 10) Tube retrieved for DNA extraction or bar-coded storage at -80 degrees and archiving via "Freezerworks 5.3"

Payers Begin Speeding Up Payment to Physicians

“Swipe card” readers, similar systems to help physicians collect more dollars from patients

CEO SUMMARY: *Labs and pathology groups have always found it tough to bill patients and collect a high proportion of those obligations. That situation is about to change, and fast! Payers recognize that, as more consumers are required to pay higher deductibles, co-pays, and out-of-pocket expenses, they will have to offer physicians and other providers near-real time services to verify eligibility and settle claims.*

FOR YEARS, the laboratory industry has searched for effective methods to boost the collection rate from patients. It now appears health insurers will soon introduce a variety of tools that will eventually help laboratories in this effort.

The need for these eligibility and claims verification tools is a direct consequence of the growing number of patients participating in high-deductible health plans, health savings accounts (HSAs), and other forms of consumer-directed health plans (CDHPs). These new types of health insurance plans usually have one thing in common: the provider must collect substantially more money from the patient.

Patients Need To Pay More

High-deductible health plans often require the consumer to pay deductibles of \$1,000 or more before insurance coverage kicks in. HSAs may require a family to pay as much as \$5,000 out-of-pocket during the year before the insurance policy begins to pay providers.

Requirements that the patient pay high-deductibles and out-of-pocket expenses are creating a new problem for physicians. They must now organize their office to collect large amounts of money directly from the patients—preferably at the time of service, before the patient has left the physician’s office.

And remember, even as physicians must cope with this new problem, payers continue to reduce reimbursement for clinical services. This places the physician in a double-whammy. On one hand, he must collect more money than ever before from a patient. That’s never been easy, as labs can attest. Second, since payer reimbursement for clinical services is shrinking, physicians need, with some financial urgency, to collect every possible penny from patients.

Collecting from patients while they are still in the physician office is an ideal solution—but impractical for an obvious reason. Most patients don’t know what their copayment, deductible, or out-of-pocket is. That general-

ly means physicians must bill the insurer, wait weeks for a settlement, and only then can they bill the patient for the balance.

This situation has not gone unnoticed by health insurers. They recognize that high-deductible health plans and HSAs will not succeed unless the physician can do a better job of getting patients to pay the full amount owed, on a timely basis. For this reason, health insurers are introducing new systems specifically designed to help physicians more efficiently collect all the money due them from patients.

Calculating A Patient's Bill

A new system from **Companion Technologies** in Columbia, South Carolina, a subsidiary of **Blue Cross Blue Shield of South Carolina** (BCBSSC), makes it faster and simpler for a physician to collect from patients at the point of service. At the same time, this system is designed to increase the cash flow of medical group practices and other providers, like laboratories.

“What this system does on the patient side is settle the patient’s responsibility before the patient leaves the doctor’s office,” said Deryl Metze, Vice President of Electronic Data Interchange for Companion Technologies. “The system is a card reader that accepts patients’ credit, debit, or insurance cards.

Helping Docs Collect \$s

“It has a small footprint, consisting of an alphanumeric keypad, a small screen, and a printer that prints a patient receipt,” explained Metze. “It’s called the Companion Direct Point of Care system. In August, Companion began leasing this system to physicians for \$19.95 per month plus 20 cents per transaction.”

The primary objective of this new system is to let both the patient and the physician’s office staff know how

Faster Payments to Docs Is Now a Major Priority

BANKS AND INSURERS ARE DEVELOPING technology to help speed up the medical payment process. Many of these efforts center around use of smart cards that can be swiped and will eventually be used in laboratories and pathology groups across the country.

Semtek, a technology company in San Diego, California, offers a magnetic stripe card reader in a handheld computer for use in healthcare settings. The system can identify, access, and update patient’s medical records. It can also collect and process credit card data.

Several Blue Cross and Blue Shield plans are among the insurers offering swipe cards to their members. **Regence Blue Cross Blue Shield of Oregon** gives its members cards with features that allow physicians to speed up payments from health reimbursement arrangements (HRAs), health savings accounts (HSAs) or flexible spending accounts (FSAs). Also, several Regence health plans offer a stand-alone debit card that members can use to pay for out-of-pocket costs.

much the patient owes—before the patient leaves the office. It is designed to process claims in real time.

Besides the cards of BCBSSC patients, the Companion Point System also works with cards from other health plans, including **Aetna**, **Cigna**, **UnitedHealthCare**, and South Carolina’s Medicaid program,” noted Metze. “Companion Technologies is working to get the system to work with Medicare as well. Access to these insurer’s systems occurs in less than 10 seconds.

“Because the system can be used to verify eligibility and process claims

instantly in real-time, physicians' staff can collect payment at the point of care," he explained. "It's turning healthcare into a retail transaction. When you go to a retail store to buy a product, you pay for it before you leave. That's not been true in healthcare—at least until now. That's why we think doctors will love it."

Enthusiastic Response

"Indeed they do," said Marilyn Meyers, Practice Administrator for **West Ashley Family Medicine**, a four-physician practice in Charleston, South Carolina. "We absolutely love it." West Ashley Family Medicine is one of 21 beta-test sites that's been testing Companion Direct Point of Care system since February. With that test concluded, Meyers plans to recommend that the practice lease the system from Companion Technologies.

"If a BCBSSC patient does not have a swipe card, then nine times out of 10, we don't know how much the patient owes, in terms of the deductible," observed Meyers. "The situation is completely different when the BCBSSC patient does have a swipe card. Right on the spot we get a report directly from the insurer that shows how much they owe. This has proved to be quite a benefit for both our patient and our medical group."

Real-Time Eligibility

THE DARK REPORT predicts that lab executives and pathologists will be surprised at how rapidly real-time eligibility verification and real-time claims settlement becomes common in the offices of providers around the country. Payers already understand that they must help physicians collect higher copays and deductibles from patients. The examples provided in this intelligence briefing demonstrate how payers in different regions are already offering enhanced eligibility

and claims settlement services to physicians in their care networks.

Laboratories and pathology groups will be impacted in several ways from this trend. First, as greater numbers of patients grow accustomed to paying significant amounts of money to physicians, hospitals, and other providers, they will expect their laboratory provider to offer them the same eligibility verification/claims settlement service they get from the physicians.

This means labs and pathology groups must prepare to deal with patients on a cash basis. Patient service centers (PSCs) will need the capability to accept cash, credit cards, and health debit cards. PSCs will need the same kind of electronic link with payers to perform real-time eligibility verification and claims settlement while the patient is present.

Second, as consumers grow accustomed to paying more money directly to providers, laboratories and pathology groups should enjoy a better collection ratio for patient-billed services. On balance, this will be a positive development for the laboratory industry. But it represents a significant shift in mindset by both patients and providers.

In the world of consumer-directed healthcare, prices charged by providers, including laboratories, will need to be transparent and readily available to consumers. Payment—and arrangements for deferred payment—will be determined at the point of service.

Laboratories and pathology group practices should look at this as an opportunity to create competitive advantage. Rapid and effective responses to these trends will help labs and pathology groups keep existing clients, and grab more market share. **TDR**

Contact Daryl Metze at 800-288-1227 and Marilyn Meyers at 843-402-0367.

INTELLIGENCE

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



Home screening for colon cancer is about to commence on a large scale in the United Kingdom. Beginning in April 2006, two million people between the ages of 60 and 69 will be sent test kits every second year. Consumers will receive Fecal Occult Blood (FOB) test kits. They will collect their own specimens and forward them to one of five laboratories designated to conduct the test. It will cost an estimated US\$65.3 million to conduct the program during its first two years.

MORE ON: Home Testing

The United Kingdom effort mirrors a similar colorectal home screening project in the United States. Earlier this year, **Cigna HealthCare** and **Quest Diagnostics Incorporated** launched a pilot project to mail diagnostic colorectal tests to about 40,000 members in the CIGNA HealthCare of Florida HMO who are 50 or more years old and have not had a colorectal cancer screening. This pilot project is estimated to cost \$40,000 and will be jointly paid by Cigna and Quest Diagnostics.

LAB RECRUITERS SOON TO HAVE WEB .JOBS SUFFIX

Recruiting laboratory staff will become easier as the laboratory industry learns more about the new “.jobs” suffix, which is available for use on the Internet. Earlier this year, ICANN, the **Internet Corporation For Assigned Names and Numbers**, approved two new suffixes. One is “.jobs” and the other is “.travel.” Essentially, these suffixes will be used after the company’s domain name and will help job seekers find postings for available positions. URLs like *www.microsoft.jobs* or *www.intel.jobs* are already active and connect the searcher with job postings at those two companies.

ADD TO: .jobs

These two new suffixes show how the Internet is evolving. They were created because companies and job searchers both needed a more uniform method to post and access job listings. Since these suffixes can only be used in conjunction with a company’s existing domain

name, they provide an indication of how additional suffixes may be developed to create uniformity in Web site design and function. THE DARK REPORT would be interested to hear from any laboratory, pathology group, or lab vendor that already uses the “.jobs” suffix as part of its recruitment program.

FDA CLEARS POCT DRUGS-OF-ABUSE KIT

Competition in drugs-of-abuse testing remains intense. **MEDTOX Scientific, Inc.** of St. Paul, Minnesota announced FDA clearance of its new Sure-Screen® drugs-of-abuse point-of-collection test (POCT) device. MedTox says that clinical studies support the ability of Sure-Screen technology to provide lower detection levels, by an average of approximately 50% each, for marijuana, opiates, cocaine, amphetamines, methadone, benzodiazepines, methamphetamines, and MDMA-Ecstasy. MedTox believes there will be strong demand for a POCT device with a broad, 8-drug test panel and lower detection levels.

***That’s all the insider intelligence for this report.
Look for the next briefing on Monday, December 5, 2005.***



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