

From the Desk of R. Lewis Dark...

THE **RD** DARK REPORT

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

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COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher



Intense Competition for Market Share in New York

ONE OF THE MOST TURBULENT MARKETS FOR LAB SERVICES TODAY is New York City and the Tri-State area of New York, New Jersey, and Connecticut. This is ground zero in the fight for market share between **Quest Diagnostics Incorporated** and **Laboratory Corporation of America** and competition is intense. The stakes are highest for Quest Diagnostics. It has long held a dominant market position in New York City, so it has the most to lose.

Adding to the competitive pressure are the submarkets to the east and to the west of New York City itself. Located to the west, across the Hudson River, is **Bio-Reference Laboratories, Inc.**, (BRLI), which is enjoying record revenue and operating profit. (See pages 7-9.) East of New York City, **Sunrise Medical Laboratories** is prospering on Long Island. (See pages 3-4.) And now that **Sonic Healthcare Limited** of Sydney, Australia, will acquire Sunrise, the level of competition just got “kicked up a notch,” as the famous New Orleans chef Emeril Lagasse is fond of saying.

Generally, competition is good for physicians and patients. But Thomas Rafalsky, President of the **New York State Clinical Laboratory Association** (NYSCLA), observes that the current managed care contracting war between the two blood brothers may have a long-term negative financial effect on NYSCLA's independent laboratory members. (See pages 10-11.) Rafalsky also notes that, when national managed care contracts for lab testing services are priced on a formula that is a discount from Medicare fee schedules, it can be used by Medicare officials to support Medicare's plan for competitive bidding of lab testing services. And, the deeper the contract discount from Medicare fees in such contracts in the private sector, the stronger the argument Medicare officials have to support competitive bidding.

What intrigues me is how New York City and the Tri-State region have quickly evolved into probably the nation's most competitive market for lab services. LabCorp's national contract victory with **UnitedHealth** led it to open several hundred patient service centers and expand its network of rapid response labs, couriers, and sales force across Greater New York. That has been a direct challenge to Quest Diagnostics. Meanwhile, a handful of independent labs in the region, such as Bio-Reference and Sunrise, have scrambled to take advantage of the fact that changes to managed care lab networks have caused physicians to reconsider their choice of laboratory provider.

Sonic Lands In New York With Sunrise Purchase

➤ **Australia's Sonic Healthcare inks its seventh laboratory acquisition agreement in 24 months**

➤➤ **CEO SUMMARY: Sonic Healthcare Limited of Sydney, Australia, continues to open its checkbook and purchase independent laboratory companies here in the United States. The latest deal is its agreement to purchase Sunrise Medical Laboratories of Hauppauge, New York, for as much as \$168 million. This gives Sonic Healthcare a solid foothold in the Tri-State market of New York, New Jersey, and Connecticut.**

COMPETITION FOR LAB TESTING in Greater New York just heated up another notch with news that **Sonic Healthcare Limited** is buying its way into the market.

On July 5, Sonic Healthcare announced it had signed an agreement to purchase **Sunrise Medical Laboratories** of Hauppauge, New York. Based on Long Island, Sunrise gives Sonic a firm foundation to expand in the Tri-State area.

Sonic will purchase 100% of Sunrise Medical for \$148 million. The deal also includes another \$20 million for an earn-out agreement. Sunrise Medical has annual revenue of about \$75 million, and Sonic disclosed that the purchase price reflects a 9.5 multiple of earnings before interest, taxes, depreciation, and amortization (EBITDA).

There are five significant aspects to Sonic's acquisition of Sunrise Medical. First, this deal puts Sonic Healthcare squarely into one of the nation's largest urban and suburban markets. The 2000 census identified the metropolitan area of New York, Long Island, and Northern New Jersey as the biggest in the United States, with 21 million residents.

Second, the Sunrise acquisition is significant because the Long Island laboratory has earned a reputation as a tough competitor in its service area. It is well-run and provides a consistently high level of service. Further, Sunrise Medical Laboratories has a philosophy of leveraging its high service levels with effective sales and marketing. This strategy has helped the company to more than double in size during the past six years.

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Sonic Healthcare Moves Swiftly to Build a U.S. Base

Laboratory Acquisitions	Location	Date	Est. Annual \$ Revenue
Clinical Pathology Labs	Austin, TX	8/05	\$190 million
Cognoscenti Health Institute	Orlando, FL	9/06	\$15 million
Lookadoo Skyline Labs	Port St. Lucie, FL	12/06	\$12 million
American Esoteric Labs	Nashville, TX	1/07	\$100 million
Muskogee Clinical Lab	Muskogee, OK	4/07	\$15 million
Mullins Pathology & Cytology	Augusta, GA	4/07	\$17 million
Sunrise Medical Labs	Hauppauge, NY	7/07	\$75 million

Total: seven acquisitions

est. \$424 million

IN LESS THAN TWO YEARS, Sonic Healthcare Limited of Sydney, Australia, has spent an estimated \$820 million to acquire seven laboratories in different regions of the United States.



**SONIC
HEALTHCARE**

Third, it can be expected that Sonic Healthcare is buying Sunrise in order to use it as a platform for growth in the Tri-State area. As a billion-dollar, international laboratory company, Sonic Healthcare is capable of supplying additional management support and the ample amounts of capital that will be needed to expand Sunrise's presence into new service areas.

► Market Valuation

The fourth significant aspect about this acquisition is the market valuation for Sunrise, as validated by the sales price agreed to by Sonic Healthcare. As noted earlier, Sonic will pay 9.5 times EBITDA for Sunrise. This valuation multiple is significantly more than what was prevalent just five or six years earlier.

The sales price and the multiple show a continuing trend toward higher valuations for laboratory companies. Earlier this year, **Quest Diagnostics Incorporated** paid \$2 billion for **Ameripath, Inc.**, a company with annual revenue of \$750 million. Analysts estimate that this valuation was at about 10 times EBITDA. (See *TDR, April 23, 2007.*)

Fifth, this acquisition continues the rapid expansion of Sonic Healthcare into the United States. When the Sunrise deal

closes later this year, it will be at least the seventh laboratory company that Sonic has acquired since the summer of 2005. (See sidebar above.) Sonic Healthcare has only publicly announced four of its seven laboratory acquisitions.

For the two founders and owners of Sunrise Medical Labs, the agreement with Sonic Healthcare will preserve the name and operational integrity of the lab they established in 1972. CEO Larry Siedlick and President Pat Lanza will remain after the sale closes and continue to operate the business as part of the growing national network of Sonic labs in the United States.

Finally, is it coincidence that, for the second year in a row, an owner of an independent lab company spoke at the *Executive War College* and, within months, Sonic Healthcare acquired that lab? Siedlick spoke at the program in May this year, and this sale was announced eight weeks later. In May 2006, Philip Chen, M.D., Ph.D., founder and former president of **Cognoscenti Health Institute** in Orlando, Florida, made a *War College* presentation. About 12 weeks later, in September 2006, Sonic acquired Cognoscenti. Today Chen is the Vice President and Chief Medical Informatics Officer for Sonic's **Clinical Pathology Labs** (CPL) of Austin, Texas.

GE's Deal for Abbott IVD Collapses Last Week

➤ Analysts believe that, during due diligence, GE decided that \$8.13 billion was too much to pay

➤➤ **CEO SUMMARY:** *Both companies have said little about their mutual decision, announced last week, to kill the pending sale of Abbott Diagnostics and Point-of-Care businesses to General Electric. One probability is that GE decided, during due diligence, that its willingness to pay a premium price—15 times EBIDTA—was unjustified by the quality of the assets and Abbott's current affairs with the Food and Drug Administration.*

MANY WERE SURPRISED LAST WEEK when **General Electric Corp.** and **Abbott Laboratories, Inc.** announced the cancellation of the pending acquisition that would have sent Abbott's primary diagnostics and point-of-care testing businesses to GE.

General Electric had earlier agreed to pay about \$8.13 billion to purchase the diagnostics businesses which, in 2006, generated approximately \$2.7 billion in revenue. That rather high price for Abbott Diagnostics' revenue stream seems to be part of the reason why GE did not wish to finalize the purchase.

At the same time, the decision by General Electric to terminate its purchase of Abbott's main *in vitro* diagnostics (IVD) business unit and a line of point-of-care testing won't mark the end of GE's interest in creating a larger presence in the IVD marketplace. THE DARK REPORT predicts GE will continue to pursue opportunities in IVD.

In the days following the announcement of the deal's collapse, Wall Street analysts were generally in agreement about why it

had failed. Citigroup analyst Jeffery Sprague, in an investor note, wrote that this may be a "blessing in disguise" for General Electric, stating that, at a valuation that was 15 times EBIDTA (earnings before interest, depreciation, taxes, and amortization), "the Abbott business was a good strategic fit for GE, but, in our view, was not a critical asset and was very expensive. At that valuation, we believe the business and deal terms needed to be pristine for GE to proceed."

➤ "A Business In Decline"

Analyst Peter Bates in the Baltimore, Maryland, offices of **T. Rowe Price & Associates** was quite blunt, declaring that "It's good they're not buying this asset. It was a business in decline and GE should be buying back its stock." Bates' fund owns 143 million shares of GE, currently worth about \$5.7 billion.

The public statements by General Electric and Abbott Laboratories about the break-up of the deal were terse, with GE giving more of an explanation than Abbott, stating, "GE and Abbott worked diligently to complete the transaction but

were unable to reach agreement on final terms and conditions. As a result, they agreed it was in the best interests of both companies to mutually terminate their agreement and discussions.”

Glenn Navarro of **Bank of America** was more direct in his explanation for the deal’s collapse. He stated, “In talking to the company [GE], it is our sense that GE asked for additional terms that would have decreased the value of the transaction and these terms were not acceptable to the management [of Abbott].”

► **FDA Issues A Factor?**

Since the diagnostics division of Abbott Laboratories has a much-publicized history of problems with the FDA, it could be that this was one source of disagreement between the buyer and the seller. A consent decree between Abbott and the FDA is still in effect from issues that surfaced in 1999. (See *TDR*, November 22, 1999.) An Abbott spokesman said that all but one of the diagnostics division’s manufacturing sites have recently passed FDA inspection. That site is in Irving, Texas and was the subject of an FDA warning letter, dated March 13, 2007 and posted on the FDA Web site. (See *TDR*, April 27, 2007.)

Last May, General Electric CEO Jeffery Immelt, at an investor conference, noted his company’s wariness at the situation. “The complexity [of this acquisition] is really driven around it being an asset deal that has got a very complicated footprint, so there are a lot of transition service agreements,” he explained. “It being in a consent decree, as Abbott has been, clearly we are not going to acquire the company with regulatory risk. And they wouldn’t expect that either.”

There are plenty of reasons to believe that GE will continue to look for opportunities to expand its presence in the IVD market. Prior to becoming GE’s CEO, Immelt ran GE Healthcare. He is knowledgeable about the opportunities in healthcare. In fact, last week, a GE spokesperson, answering questions about

the collapsed deal, stated that GE is “committed to early health and [will] continue to invest in that strategy.”

There are other IVD companies which could give GE an immediate and significant market position in *in vitro* diagnostics. For example, **Beckman Coulter Corporation**, with revenue of \$2.57 billion last year, has a market capitalization of about \$4.26 billion. **Dade Behring, Inc.** which reported 2006 revenue of \$1.78 billion, has a market cap of almost \$4.65 billion. Even **Quest Diagnostics Incorporated** could be a merger/acquisition candidate if GE wanted a presence in the service side of clinical diagnostics. During 2006, Quest Diagnostics reported revenue of \$6.24 billion and its market cap is currently in the range of \$10.6 billion.

These examples are simply to demonstrate that GE has the buying power to consider such acquisitions. It has many options to consider if it wanted to buy its way into the IVD industry. Thus, during the next 24 months, the laboratory profession should not be surprised at any kind of merger or acquisition GE develops as a way to boost its presence in *in vitro* diagnostics.

► **Abbott Diagnostics’ Future**

For Abbott Laboratories, the future of its IVD business division is probably now more complex. For one thing, Abbott corporate has signaled its willingness to divest the business. One consequence of the decision to sell to General Electric is that some productive executives and sales producers at Abbott Diagnostics will be more amenable to jumping ship and joining other companies that promise stability.

It may be also be true that, until Abbott Diagnostics resolves its issues with the FDA and is released from the current consent agreement, it will be a tough asset to sell. Further, it is still uncertain how laboratory customers and prospects will react to the fact that Abbott Diagnostics has been put up for sale.

BRLI Seizes NYC Share In Two-Stage Effort

➤ **Regional lab company benefits from turmoil from managed care contract changes in NYC**

➤➤ **CEO SUMMARY: Bio-Reference Laboratories, Inc., (BRLI) reported record financial results for its most recent fiscal quarter last month. Much of this success is rooted in BRLI's discipline in defining itself as a local laboratory and using enhanced lab testing services to align itself as a clinical and operational partner with client physicians in the community. Here is an assessment of why this business strategy is proving effective.**

IT WAS A RECORD QUARTER for **Bio-Reference Laboratories, Inc. (BRLI)**, and the opportunities created in New York City from managed care contract changes played an important role. The lab company announced that revenue and earnings were at an all-time high, triggered by uncommonly strong growth in specimen volume since the first of the year.

For its second quarter ending April 30, Bio-Reference reported revenue of \$60.9 million, which is an increase of 29% over the \$47.2 million it posted in the same quarter last year. Operating income was up by 32%, at \$5.9 million this year compared to \$4.4 million for Q2-06.

Particularly noteworthy is the increase in patient volume. This number increased more than 19%, to 921,000 in the current quarter from the prior year second quarter total of 772,000. For the full six months of this fiscal year, patient count rose by 17% compared to the first six months of the 2006 fiscal year.

Even as Bio-Reference captured new patients, it was increasing its revenue per patient. The Elmwood, New Jersey-based

lab company noted that revenue per patient was \$65.59, a respectable increase of 8% over the \$60.59 reported for the same quarter of the prior fiscal year.

This strong performance across several key performance measures is not a coincidence. Among the laboratories serving Greater New York, Bio-Reference was uniquely positioned to extract maximum benefit from turmoil in this region triggered by the managed care contracting war between **Laboratory Corporation of America** and **Quest Diagnostics Incorporated**.

➤ **Business Strategy**

To understand why BRLI is delivering these sustained gains in specimen volume, operating margin, and average revenue per patient, it is helpful to explain how Bio-Reference positions itself in the New York marketplace. Bio-Reference Labs is pursuing a three-pronged business strategy.

First, Bio-Reference acknowledges that it is, at its most basic, a regional commercial laboratory company which provides a broad range of testing services to office-

based physicians in the Greater New York market. To succeed in this effort, it works earnestly to deliver a consistent and high level of service to its client physicians.

Second, BRLI is committed to using effective sales and marketing to build its business. This strategy runs counter to its larger public lab company competitors, which have fueled their growth with a steady flow of lab acquisitions. For Bio-Reference, however, to succeed as a local laboratory, it must be particularly good at sending sales reps into physicians' offices and converting prospects into active accounts.

► **Esoteric Testing Services**

The third strategy is to leverage the existing infrastructure to offer specialized esoteric diagnostic services. This helps BRLI differentiate itself clinically with its client physicians, as well as helping to build average revenue per requisition. This strategy is based on another clever business approach, which is to create a national business from each of these subspecialty esoteric laboratories it creates. In its focused areas of oncology (primarily hematopathology), correctional healthcare, genetic testing, infectious disease testing, and women's health, BRLI is a top national provider in each category.

As volume in these specialized areas increases, Bio-Reference will retain nationally-known experts to perform the testing. It then sells these specialized esoteric services nationally, using a team of dedicated sales reps to build market share across the country.

The successes of these interlinked business strategies show up in Bio-Reference's quarterly earnings report. BRLI noted that esoteric business was 44% of revenues for the second quarter of the current fiscal year. That is atypical of a local commercial laboratory company. BRLI's esoteric testing covers oncology, genetics, toxicology, and immunology.

These are the business reasons why Bio-Reference seems to be getting its share of the **UnitedHealth** business in New York City that came up for grabs on January 1, when Quest Diagnostics ceased to be a contract lab provider for UnitedHealth.

► **UnitedHealth Opportunity**

"When United Healthcare made their announcement about the exclusive contract, we already had a strong position in New York, as well as surrounding markets," said BRLI President Marc D. Grodman M.D. "Still, we recognized that the new UnitedHealth contract was going to disrupt the status quo. We've worked hard to take advantage of that opportunity."

Grodman declined to discuss how much of the increased patient volume in recent months is due to convincing New York-area physicians to steer their UnitedHealth patients to Bio-Reference Labs. However, he did provide a useful insight about how Bio-Reference has benefited from the market turmoil related to the UnitedHealth contract.

"Independent of our additional expenses in sales and marketing, we experienced a tripling in the amount of money we spend setting up new accounts in the region during the past quarter," he observed. "That is four times as much as we spent in earlier years in our local market."

"That money goes for hardware, interfaces, and other system requirements required to set up new accounts," Grodman continued. "We did what we had to do to make the most of this opportunity."

► **"Are You A Network Lab?"**

Grodman acknowledged that the months following the news of the new UnitedHealth contract were busy. "We consider this phase one of the opportunity to capture new business," noted Grodman. "As physicians reacted to the new UnitedHealth contract, we were constantly answering the question of 'Are you a network provider?' We have survived and thrived through all of that."

“Now we are working on phase two in how we build long term relationships with these physicians,” he continued. “We are going back to all our clients—existing and new clients—to educate them about the specific ways that we can help them improve patient care.

“BRLI has an inherent belief that physicians want to be treated as professionals and it constantly strives to provide programs that physicians will easily recognize as opportunities to provide better, more efficient healthcare,” observed Grodman. “Unique services, such as our Women’s Health Initiative and our ACT (Advanced Cardiovascular Testing) program, are both patient- and physician-centric solutions. These appeal to physicians’ intellect, curiosity, and concern for patient care.

“Our goal is for physicians to recognize us as a superior laboratory,” he added, “one that provides them a full menu of routine, reference, and esoteric testing to advance the clinical effectiveness of their medical practice.

“We want physicians to consciously recognize these attributes about Bio-Reference Labs. That moves us beyond a perception that we are simply a lab which is an accepted provider for many health plans,” Grodman said. “This is a key point in our strategy. We don’t try to be everything to everyone. We do a number of things very well and we will do them for you day in and day out.

“Don’t forget, we have a long track record over the past 13 years of 20% compounded annual growth,” Grodman said. “We’ve grown in good times and bad times, and we’ve done it by appealing to physicians as a better alternative than most other lab companies.”

➤ Adding Value

“We believe the reason that Bio-Reference is strong at winning new client accounts is rooted in the value proposition it presents to physicians,” observed Grodman. “It is a simple mindset, but one which requires diligence to execute and sustain. The usual

mindset of a doctor is to select a laboratory that can service all his patients as a contract provider. Bio-Reference Laboratories is more than that.

“Let me tie these two business strategies back to the UnitedHealth contract, because they explain why we were effective at expanding our share of the market in Greater New York,” offered Grodman. “At the time the UnitedHealth contract was announced, it triggered an outcome that was beneficial to us.

“When physicians faced the fact that their existing laboratory provider would no longer be in the UnitedHealth network, this was a disruptive event that we could use to our advantage,” he explained. “It caused physicians to think about the contracts they had for lab services and what they wanted from a lab. This gave our sales team the opportunity to step in and present Bio-Reference Laboratories as a lab partner that can help them deliver quality patient care.”

➤ Local Lab Serving Local Docs

Other local laboratories and hospital outreach programs should take inspiration from the success of Bio-Reference Laboratories. Like them, it has a local market focus. It enjoys sustained growth in specimens, revenue, and operating profit because it emphasizes the clinical value added it provides to its client physicians.

It is important that lab administrators and pathologists also recognize how a professionally-managed sales force plays an essential role in this strategy. Sales reps are the front-line in building relationships, educating the physicians about the clinical advantages of using Bio-Reference Laboratories, and helping physicians become comfortable with their decision to switch away from their existing laboratory to begin using Bio-Reference. These business strategies explain why Bio-Reference Laboratories has enjoyed great success during the recent disruptions in Greater New York. **TDR**

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Exclusive Lab Contracts Have Consequences

► Recent contract awards by UnitedHealth and Aetna drive intense competition in New York

►► **CEO SUMMARY:** *During the past seven months, competition in the Northeast has intensified. Decisions by UnitedHealth and Aetna to exclude a national laboratory from their respective provider panels has forced many physicians to reconsider their choice of laboratory provider—creating an opportunity for independent lab companies that are regional network providers. However, acceptance of contract prices based on a discount from Medicare fees may have negative consequences.*

NEW YORK'S LABORATORY SERVICES MARKET is almost seven months into a free-for-all fight for market share. The trigger was managed care contract decisions by **UnitedHealth Group, Inc.**, and **Aetna, Inc.**, to grant exclusive national status to **Laboratory Corporation of America** and **Quest Diagnostics Incorporated**, respectively.

Both of the national laboratory companies are using their exclusive national contract status as a lever to wrest office-based physician business away from their competitors. At the same time, a number of independent laboratory companies in New York hold regional contracts with UnitedHealth and Aetna as in-network lab providers. This allows them to also compete for business in most regions of the state.

However, the latest round of managed care contracting wars is having unwelcome consequences to the lab industry in New York State. According to Thomas Rafalsky, long-time President of the **New York State Clinical Laboratory Association** (NYSCLA), these exclusive contracts have driven prices down and driven lab work out of New York.

"Most independent laboratories in New York hate these exclusive contracts," Rafalsky said. "Recent decisions by major payers to further restrict access to their laboratory provider networks are harmful to the independent lab sector.

"At the same time, the national labs have intensified their bidding war, causing payers to drive down the prices they offer all laboratories," he continued. "We've heard that the prices on the exclusive contracts are based on a fairly low percentage of Medicare rates. That means the national labs have created a bidding environment almost like a price war. In that environment, the Medicare program would be more than justified to use a competitive bidding approach for lab services.

► Competitive Bidding Threat

"Across the laboratory industry, there is universal opposition to the pending Medicare demonstration project for competitive bidding of laboratory test services because laboratory services are not a commodity and should not be treated like a commodity," observed Rafalsky. "However, in the current managed care

contracting and pricing environment, Medicare may ask itself: ‘Why can’t these services be put out for bid?’ We all know that, to properly serve the lab testing needs of clinicians, it requires a great deal of personal attention and support. But, when a major lab bids a percentage of Medicare prices to get an exclusive contract, why wouldn’t Medicare want to benefit from that same price point?”

Rafalsky’s comments notwithstanding, some independent laboratories are taking advantage of the most recent managed care contracting wars between the two blood brothers. **Bio-Reference Laboratories, Inc.**, (BRLI), of Elmwood, New Jersey, reported an increase of 29% in revenue for the quarter that ended April 30 compared with its results for the same quarter last year. Operating income rose by 32% and patient volume rose by 19%. (See pages 7-9.)

➤ **Finding Opportunities**

Another company finding a favorable market for lab services is **Sunrise Medical Laboratories** in Hauppauge, New York. Last week, **Sonic Healthcare Limited** of Melbourne, Australia, agreed to acquire Sunrise for \$148 million. (See pages 3-4.)

For Sunrise CEO Larry Siedlick, exclusive contracts do not necessarily mean that all other labs are shut out. “Certainly we have experienced nice growth since both of those situations developed earlier this year,” he said.

“These contracts are exclusive but in reality, it depends on what you mean by ‘exclusive.’ One company might say, ‘I’m the exclusive national provider now,’ and you could read that in two ways,” said Siedlick. “It can mean you’re the only lab that has an exclusive contract with a particular managed care plan to provide services in every region of the nation. Or it can mean that you’re one of the network labs, but you are the only lab with the infrastructure and ability to provide nationwide coverage.

“The big national labs like to say they are the exclusive national providers

because that can cause doctors to believe that no one else is in the network,” Siedlick explained. “But all the communications you see from United Health and Aetna make reference to the fact that regional laboratories are participating as part of those plans. That’s where there are openings for labs like ours.

➤ **Compare Service Levels**

“Our model is to go and get that work from the referring doctors for ourselves,” Siedlick said. “And so far, we’ve been successful. Typically, step one is to make the doctors aware that your lab is a contracted, network provider. Step two is where you can come out a winner as the physicians compare service levels and understand why your lab is able to provide high-quality service.

“In addition, doctors are splitting specimens when they can,” Siedlick commented. “In earlier years, when there were six to eight lab companies operating nationwide, these labs essentially taught referring doctors to use multiple laboratories. In the Long Island and New York City markets, most physicians use multiple laboratories.”

➤ **Limiting Access To Patients**

For Rafalsky, however, the exclusive contracts have not created an opening in the market. “Exclusive contracts haven’t opened up any avenues of communication between the labs that were excluded and referring physicians,” Rafalsky commented. “When the networks get constricted and labs get eliminated, that’s a negative because access to those test referrals can be the difference between financial life and death for some independent laboratories.”

What remains true for the lab industry is that competition for physician test referrals remains intense. As Rafalsky notes, the current managed care contracting war is likely to cause some casualties among independent labs in New York State. **TDIR**

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Lean/Six Sigma In Labs Becomes More Common

► **Lab Quality Confab in Atlanta on Sept. 19-20 is first conference devoted to quality management**

►► **CEO SUMMARY: Across healthcare, laboratories, hospitals, and health systems are leading the drive to incorporate quality management methods into clinical services and daily operations. This fall, in Atlanta, the Lab Quality Confab will provide a detailed look at this trend, with 50 speakers, master classes, case studies, full-day workshops, an exhibit hall, and even Lean and Six Sigma poster sessions with trophies and cash awards.**

ONE OF THE MOST IMPORTANT TRENDS in laboratory management is the growing acceptance and use of quality management methods, including Lean, Six Sigma, and ISO 15189.

It was only in 2002 and 2003 that a handful of hospital laboratory organizations in the United States became the first in the nation to embrace and use Lean and Six Sigma to improve individual work processes and trigger substantial improvements in quality, productivity, cost reduction, and staff morale. (See *TDR*, September 8, 2003.)

In the five years since these pioneers proved the value of Lean and Six Sigma in laboratory and pathology operations, a steadily growing number of labs and hospitals have introduced quality management programs into their organizations. As a trend, use of Lean, Six Sigma, and similar methodologies is no longer restricted to first-mover and early-adopter laboratories. It is going mainstream across both the laboratory profession and the hospital industry.

That is the inspiration for the upcoming *Lab Quality Confab* (www.labqualityconfab.com),

a conference devoted to quality management in diagnostic medicine. It will take place on September 19-20, 2007, at the Westin Peachtree Hotel in Atlanta.

Produced by THE DARK REPORT, it is another lab industry first. There will be more than 50 speakers with special sessions and case studies on a full range of Lean/Six Sigma projects that cover various aspects of clinical services and operational processes.

► Major Survey Across Industry

“To assemble a faculty of 50 speakers required many phone calls and discussions with *in vitro* diagnostics (IVD) manufacturers, lab industry consultants, labs, and pathology groups currently using Lean and Six Sigma in their respective organizations,” stated Robert L. Michel, organizer of *Lab Quality Confab* and Editor-In-Chief of THE DARK REPORT. “By itself, this was a major survey of the quality management trend across the laboratory profession.

“Three things became obvious as a result of this interaction with such a wide spectrum of people and organizations,” continued Michel. “First, the number of

Quality Management and Continuous Improvement Are Themes for First-Ever Lab Industry Quality Confab

WHEN THE *LAB QUALITY CONFAB* CONVENES IN ATLANTA ON SEPTEMBER 19-20, 2007, it will be the first-ever national lab industry meeting devoted exclusively to use of Lean, Six Sigma, and continuous improvement. It is a conference with activities and education tailored to the specific needs of all quality practitioners in laboratories or hospitals—from the CEO and senior administrators, pathologists, and lab managers, to Lean and Six Sigma practitioners, vendors and consultants. Get the full details by visiting www.labqualityconfab.com.

September 19—Day One

7:00 AM–8:50 AM

Master Class Sessions and Lean/Six Sigma Poster Session

9:00 AM–12:00 PM

General Session

12:00 PM–1:50 PM

Exhibition and Lunch

2:00 PM–4:50 PM

Concurrent Breakout Sessions

5:00 PM–5:40 PM

General Session

5:45 PM–8:00 PM

GRAND RECEPTION & EXHIBITION

September 20—Day Two

7:00 AM–8:50 AM

Master Class Sessions and Lean/Six Sigma Poster Session

9:00 AM–12:00 PM

General Session

12:15 PM–1:15 PM

Lunch

1:30 PM–3:20 PM

Concurrent Breakout Sessions

3:30 PM–4:00 PM

General Session

September 18—Pre-Event

Optional Seminars
(Must pre-register)

8:30 AM–5:00 PM

Leveraging Lean/Six Sigma Methods When Expanding Laboratory and Molecular Services

1:00 PM–5:00 PM

Proven “Best Practices” in Lean: Putting the Secrets of the Pros to Work in Your Clinical Laboratory Workflow

September 21—Post-Event

Optional Workshops
(Must pre-register)

8:00 AM–4:30 PM

Change & Transformation: Preparing & Leading Your Health Organization on a Successful Quality Journey

8:00 AM–4:30 PM

Lean Bootcamp: Achieving Mastery with Concepts, Implementation, and Outcomes

Lab Quality Confab

on Quality Management in Diagnostic Medicine

September 19-20, 2007 • Westin Peachtree Hotel • Atlanta

For information and to register, visit www.labqualityconfab.com

laboratories and pathology groups actively using Lean, Six Sigma, and process improvement methods today is much greater than the popular wisdom—and the speed of adoption continues to accelerate.

“Second, labs are enthusiastically engaging IVD manufacturers and consultants to come in and help teach and implement these management approaches,” observed Michel. “This happens in one of two ways. It may be an engagement to do a single project, designed to be a one-shot improvement effort. Alternatively, some laboratories and hospitals are ready to

make a top-down culture change. These organizations are engaging experts to help them implement and sustain an on-going, organization-wide improvement program.

“The third finding is a powerful insight: consultants and their lab clients report an almost 100% rate of success at applying Lean, Six Sigma, and process improvement methods and achieving the planned outcomes!” said Michel.

“Let me restate it another way, for emphasis,” he continued. “I did not learn of a single ‘failure’ by labs and hospitals that used Lean and Six Sigma methodol-

ogy. When these principles and tools are applied appropriately, there is always measurable improvement in the targeted outcomes.”

► Continuous Improvement

Attendees at **Lab Quality Confab** will have the opportunity to confirm these findings for themselves. There will be master classes taught by experts in Lean, Six Sigma, and process improvement. These sessions provide hands-on instruction in the tools, philosophies, and methods of continuous improvement.

More than 20 break-out sessions will showcase case studies and specific improvement projects conducted by laboratories and hospitals. The outcomes are remarkable. At **PAML**, in Spokane, Washington, the courier and logistics department has integrated Lean/Six Sigma methods with a sophisticated informatics capability. Currently deployed across 125 routes in Washington and Idaho, PAML is achieving 5+ Sigma in the daily performance of its courier division.

Another case study will be presented by **North Shore Long Island Jewish Health System** of New Hyde Park, New York. It is using improvement principles to develop laboratory best practices at one site, then rapidly introduce them in the labs of each of the system’s 15 hospitals.

Other case studies will cover patient ID, phlebotomy, processing, core lab and automation, histology, surgical pathology, hematology, and even laboratory sales and marketing. **Sonora Quest Laboratories**, winner of the Arizona Quality Program Governor’s Award, will share its experience at using client, patient, and staff surveys to drive continuous improvement against world class benchmarks.

At the general sessions, Lab Quality Confab will feature one of the first lab industry presentations by **General Electric** since it took steps to expand its presence in *in vitro* diagnostics. Marc E. Cottle, Service Business Operations

Leader, IVD Integration at GE, will discuss how GE’s quality journey led it to expand its presence in healthcare.

Another keynote speaker is Barton Gill, Managing Principal/Senior Director, Consulting Solutions, **Premier, Inc.** A self-described pragmatic improvement specialist, he will discuss how and why ever-growing numbers of hospitals, laboratories, and physicians are incorporating continuous improvement into their clinical and operational activities.

One unique opportunity at **Lab Quality Confab** will be poster sessions of Lean, Six Sigma improvement projects. To recognize the most outstanding examples, Lab Quality Confab will offer trophies and cash awards totaling \$6,000. Judging will take place in two categories: projects in clinical laboratories and projects involving anatomic pathology services, including pathology group practices. Poster presenters must be invited. A special page at www.labqualityconfab.com has full details and instructions on how to submit an abstract for consideration for an invitation.

► To Help Lab Professionals

“Lean/Six Sigma poster sessions add additional learning beyond the more than 50 participating labs, IVD firms, consultants, and hospitals at the **Lab Quality Confab.**,” noted Michel. “The organization of this program is designed to help laboratory professionals in two ways.

“One, anyone actively involved in Lean/Six Sigma projects will find everything they need to advance their skills, ability, and network of fellow quality practitioners,” Michel said. “Two, for anyone ready to start their quality journey, they can gain the knowledge, meet the experts, and learn how to successfully plan and implement projects.

“Another fact sets this gathering apart from most lab industry meetings,” concluded Michel. “Lab leaders already working with Lean and Six Sigma are passionate about this subject. For that reason, this will be an enthusiastic gathering.”

Growing NeoGenomics Offers FISH Test TC/PC

➤ Growing lab company emphasizes complex genetic and molecular assays

➤➤ **CEO SUMMARY:** *This specialty lab testing company now has laboratories in Fort Meyers, Florida; Nashville, Tennessee; and Irvine, California. It recently beefed up its executive ranks and is adding to its menu of genetic and molecular assays. In December, 2006, NeoGenomics rolled out a nationwide TC/PC program in FISH testing that allows community hospital-based pathologists to perform and bill for professional component (PC) services.*

SINCE ITS FOUNDING IN 2001, NeoGenomics, Inc. of Fort Meyers, Florida has quietly developed a growing business in genetic testing and molecular diagnostics.

A public company projected to exceed \$15 million in revenues during 2007. NeoGenomics trades under the symbol NGNM.OB on the OTC Bulletin Board (OTCBB). Its recent market capitalization was about \$50 million.

An interesting fact sets NeoGenomics apart from several of the anatomic pathology companies launched in the past decade. It has not accepted large amounts of venture capital money. In contrast, **US Labs, Inc.** absorbed more than \$70 million in equity investments before its sale to **Laboratory Corporation of America** in 2005. **Clariant, Inc.** (formerly **ChromaVision Medical Systems, Inc.**) is another example of an anatomic pathology company that has attracted as much as \$80 million in equity capital. (See *TDRs, January 3, 2005 and August 30, 2004.*)

“At NeoGenomics, the emphasis is on genetic testing and selected molecular assays,” stated Robert Feeney, Ph.D., Vice

President of Sales and Marketing at NeoGenomics. “Our strategy is to be a national laboratory with a regionalized focus. We want to be a resource for community hospital-based pathologists and not compete against them. We currently operate laboratories in three distinct regional markets. They are Nashville, Tennessee; Irvine, California; and Fort Myers, Florida.”

➤ Three Primary Types of Tests

NeoGenomics emphasizes cytogenetics, Fluorescent In Situ Hybridization (FISH), and flow cytometry. “FISH testing is a major product line for us,” explained Feeney. “We provide HER2 testing, bladder cancer testing with the **UroVysion** assay, and hematopoietic testing.”

To further its goal of supporting pathologists serving community hospitals, last December, NeoGenomics launched a TC/PC program in FISH testing. “NeoGenomics will provide the technical component (TC),” noted Feeney. “Our online reporting system forwards the case materials to the referring pathologist, allowing him or her to provide the professional component (PC) and bill for that service.

“This arrangement has been well received,” he added. “But it is only available to pathologists with the demonstrated proficiency to handle these types of cases.

“Strong demand for our TC/PC FISH arrangements led us to put a unique training program in place. NeoGenomics provides period proficiency testing to ensure consistency and accuracy of test results for any pathologist interested in working with FISH testing,” stated Feeney.

► Training To Read FISH

“Currently we conduct several training courses per month,” he continued. “It provides smaller pathology groups with a way to develop FISH skills within their practice. Once the competency of an individual pathologist is demonstrated, NeoGenomics will participate in a TC/PC arrangement and this pathologist is then approved to sign out FISH cases.”

Feeney noted that, as part of the process of demonstrating proficiency, the pathologists are tested for color blindness. “Up to 8% to 12% of males and about 0.5% of females can be color blind for red and green,” he commented. “Over the course of doing this testing, we’ve determined that several pathologists interested in learning how to read FISH tests were color blind—and were unaware of how their condition would affect interpretation of cases.”

A key part of NeoGenomics’ business plan is to offer complex esoteric testing. Its current test mix produces an average of 1.38 tests per requisition, with an average revenue per requisition of \$668.01. One reason it recently opened its new laboratory in Irvine, California is to position itself to serve the market for clinical trials and provide research and development activities for the company.

NeoGenomics has attracted several veteran lab industry executives. The company’s President and Chief Scientific Officer is Robert P. Gasparini. Previously, Gasparini was Director of Genetics for **US Labs, Inc.** Prior to that, Gasparini was Molecular

Marketing Manager for **Ventana Medical Systems, Inc.** Feeney, NeoGenomics’ Vice President of Sales and Marketing, formerly held positions at US Labs and **Impath, Inc.**

Currently about 50% of NeoGenomics’ specimen volume originates from Florida. It has referring clients in 17 states. NeoGenomics is in the midst of expanding its service menu to include additional hematopathology testing. Last fall, the firm hired hematopathologist Frank Yang, M.D., Ph.D. to spearhead the delivery of the new hematology/oncology testing services. NeoGenomics also brought aboard Matthew Moore, Ph.D., specifically to help develop new diagnostic assays.

Besides the addition of these scientists, NeoGenomics has also beefed up its sales force. “We now have 10 people in our sales organization and intend to nearly double that by year’s end,” explained Feeney. “We want to use our labs in Nashville, Irvine, and Fort Meyer as selling springboards into the regional markets that each is positioned to serve.”

► Business Strategy

One noteworthy difference between NeoGenomics and some competitors is the fact that NeoGenomics has yet to accept dilutive capital investments from professional investors. To the contrary, it runs on a tight budget and relies on internal growth to help fund ongoing expansion. For this strategy to succeed, NeoGenomics will need to sustain a highly-effective sales and marketing program. In particular, its sales staff must acquire new client accounts in a cost-effective manner.

AS THE DARK REPORT has pointed out, some pathology companies launched during the past 10 years burned through their venture capital funding and never delivered a satisfactory return on investment (ROI) to their investors—primarily because they overspent to acquire new client accounts.

TDR

Contact Robert Feeney, Ph.D., at 239-690-4235 or email rfeeney@neogenomics.org.

Lakewood Pathology Changes Leadership

➤ **Doug Berg assumes CEO duties, Tim Brodnik joins the Board of Directors**

➤➤ **CEO SUMMARY:** *Following the arrival of a new majority owner and a capital commitment of \$50 million last year, Lakewood Pathology Associates has taken additional steps to pursue growth. Lakewood plans to acquire small to mid-sized companies that are complementary to its position in the anatomic pathology markets, particularly in the subspecialties of hematology and oncology.*

FOLLOWING A MAJOR CASH INFUSION by its new majority shareholder last year, **Lakewood Pathology Associates, Inc.** (LPA), of Lakewood, New Jersey, recently announced leadership changes in its executive suite, along with a new member on its board of directors.

The new CEO is Doug Berg, who stepped up from his existing position at Lakewood Pathology as its Chief Development Officer. The new board member is Timothy Brodnik. The CEO change was triggered by the resignation of Lakewood Pathology's former CEO, Raza Bokhari, M.D., who will continue to serve as a director on the board.

These changes come one year after the company got a new majority owner, **Water Street Healthcare Partners** of Chicago, Illinois, a private equity firm focused exclusively on healthcare. The signs are clear: new leadership and a private equity partner usually mean a new plan is in place to accelerate growth.

"Our goal is to be a leading player and contributor in anatomic pathology services," Berg continued. "Lakewood Pathology is ready to pursue its next phase of growth.

"Strategically, we are investing into three business areas," explained Berg. "First, we will expand the facilities at our laboratory in Lakewood, New Jersey. We have a solid base of urology and gastroenterology clients and we want more capacity to take on additional specimen volume.

"Second, we are recruiting additional experienced professionals and want to be associated with people who have a track record of success in the industry," Berg commented. "One example is the addition of Tim Brodnik to our board, where he can provide strategic input and guidance.

"Third, we are prepared to acquire other laboratories," Berg said. "This will help us achieve two primary business objectives. One, we are ready to open up diagnostic services in hematology-oncology. This is one of the fastest-growing sectors in anatomic pathology and we want to take advantage of that.

"We are ready to expand outside our core markets in the Northeast to develop a physical presence in other regions across the United States," he said.

Acquisitions will be a primary way to accomplish these growth strategies. "Our

ideal profile is a small to mid-size anatomic pathology company,” added Berg. “We are interested in subspecialty expertise and an established market presence in specialty pathology services, particularly in hematology and oncology. We are already pursuing several attractive prospects.

► Seeking High Performers

“Leadership is one key to help us achieve our ambitious growth goals,” observed Berg. “The addition of Tim Brodник to our Board of Directors gives us access to his experience and perspective in building a successful lab business.”

Brodnik’s participation in Lakewood Pathology’s board is noteworthy, especially since he has kept a low profile after, as the CEO of **American Medical Laboratories, Inc.** of Chantilly, Virginia, he led its sale to **Quest Diagnostics Incorporated** for \$500 million in 2002. (See *TDR*, February 18, 2002.)

Lakewood Pathology Associates has posted rapid growth in specimen volume and revenue in recent years. Berg’s challenge is to sustain that pace. “We’ve learned that a key to success in the lab business is to have the right culture and that requires a focus on people,” he said. “It means adding talented individuals and putting people first, be they customers, employees, suppliers, or health insurers. Such a culture allows your company to provide excellent service and introduce innovations into the marketplace which add value to customers.”

► Positioned For Growth

“Given the nature of the anatomic pathology business, we believe we are well positioned for growth,” Berg continued. “Anatomic pathology has some of the most attractive demographic potential of the entire diagnostic testing market. For example, among the segments of clinical, esoteric, and AP, we believe AP is the fastest-growing segment of the three. And within AP, certain segments, such as hematology-oncology, are growing even faster.

Berg and Brodnik Bring Experience to Lakewood

BEFORE JOINING **LAKWOOD PATHOLOGY ASSOCIATES**, Doug Berg, the new CEO of the anatomic pathology company in Lakewood, New Jersey, held executive positions at leading laboratory companies and *in vitro* diagnostics firms.

Previously, Berg served as the Corporate Vice President of Sales and Marketing at Quest Diagnostics Incorporated. He also served in senior leadership roles at **Dade Behring**, **Baxter**, and **American Hospital Supply Corporation**.

Incoming director Timothy Brodnick is another lab industry executive with deep experience. He was the Corporate Director of Sales and Marketing at **National Health Laboratories** and **Laboratory Corporation of America**. In 1997, he was part of an investor group that acquired American Medical Laboratories, Inc. (AML) of Chantilly, Virginia. He served as AML’s CEO until it was acquired by Quest Diagnostics in 2002.

The changes we are making will position us to take advantage of these opportunities.”

Armed with a capital commitment of \$50 million from Water Street Healthcare Partners, Lakewood Pathology Associates certainly has the capital to pursue its growth strategy. At the same time, it will face increased competition from other national anatomic pathology companies targeting these same specialty markets.

Another challenge that confronts LPA and other national AP companies is the interest by urology and gastroenterology groups to establish in-house AP labs. As this happens, it reduces the number of cases referred to national AP labs. **TDR** Contact Doug Berg at dberg@lakewood-path.com.

INTELLIGENCE

LATE & LATENT

Items too late to print,
too early to report



Another example of the globalization of laboratory testing services is the just-announced acquisition of laboratory middleware provider **P.G.P. s.a.**, of Brussels, Belgium, by **Data Innovations, Inc.**, of South Burlington, Vermont. Data Innovations states that the acquisition now gives it “unprecedented worldwide reach” in the laboratory middleware market. Combined, the two companies have 6,500 middleware systems installed in 49 countries.



Ventana Opposes Roche's Hostile Takeover Offer

In June, **Roche Holdings, AG** announced a tender offer worth \$3 billion to purchase 100% of the shares of **Ventana Medical Systems, Inc.** of Tucson, Arizona. Last week, Ventana's board of directors issued a public statement recommending that its stockholders not sell their shares to Roche. Expect several more twists in this story before a final outcome is reached.



METAGENOMICS WILL EXPAND MICROBIOLOGY

Metagenomics is an emerging field of science with the potential to expand the specialty of microbiology. Metagenomics describes study of the communities of microbes in the human body and how they interact to perform such functions as fighting disease. A recent report from the **National Research Council** reveals that most microbes were previously unknown species and cannot be cultured. In a study of obesity, for example, researchers suggested that those who are overweight carry different microbes than lean people carry. The kinds of microbes that obese humans had in abundance break down food more efficiently than other microbes.



ADD TO: MICROBES

Humans have 10 times as many microbial cells as human cells! The microbial cells include bacteria and yeasts and help make vitamins and amino acids that

human cells can't produce. The report said there are billions of benign microbes in the body that help digest food, break down toxins, and fight disease. Microbes are used commercially to make antibiotics, enhance crop production, and produce biofuels. The report, *The New Science of Metagenomics: Revealing the Secrets of Our Microbial Planet*, is available from the National Academies Press (www.nap.edu).



DARK DAILY UPDATE

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

...the release of the draft bidder's package for the planned Medicare clinical laboratory services competitive bidding demonstration project and today's meeting in Baltimore for lab industry comments.

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

***That's all the insider intelligence for this report.
Look for the next briefing on Monday, August 6, 2007.***

It's New!

PREVIEW #2

Lab Quality Confab

September 19-20, 2007 • Westin Peachtree Hotel • Atlanta Georgia

General Electric's Mark E. Cottle on...

General Electric's Quality Improvement Journey and How it Intersects with Healthcare and *In Vitro* Diagnostics

In recent years, General Electric Co. (GE) has made several high profile acquisitions to expand its presence in healthcare. Learn why GE's quality journey led it to enter the *in vitro* diagnostics industry. Explore GE Healthcare's preventative health strategy and its foundations in GE's much-respected management culture, along with its incorporation of Six Sigma and Lean as the cornerstones of its quality and process improvement mindset. Understand GE's internal focus on continual improvement of its operations (manufacturing, financial, and commercial). Gain insights on how GE Healthcare expects healthcare providers will develop and expand their use of quality and process improvement methods.

*Get full program details and register now:
visit www.labqualityconfab.com*

UPCOMING...

- Roche Pursues Ventana with \$3 Billion Offer: Why Money Is Pouring Into Molecular Diagnostics.**
- Pros and Cons of Bidding for TC/PC Contracts: Secrets Every Pathologist Should Know.**
- CMS Proposes New Stark Language: Is It Sending a Signal to Labs and Specialty Docs?**

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