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From the Desk of R. Lewis Dark...

THE DARK REPORT

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

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Why You Rely on a Vigilant Lab Industry Press

AS YOU WILL READ ON PAGE 9 of this issue, THE DARK REPORT was recently honored by a national news association, which awarded it first place for "Best Investigative Reporting" against some tough competition.

Indulge me, for a moment, as I explain to you why this is a big deal. As a laboratory leader, you cannot make the best decisions if you lack accurate and timely news and understanding about current developments in the laboratory testing marketplace and the healthcare system it serves.

In fact, when there is a lack of informed news and understanding, it becomes easier to make the wrong business decision, with dire consequences to your laboratory, your loyal employees, and probably your personal career status. And that is why THE DARK REPORT, and its peer news sources covering the lab testing industry, are essential partners in your success.

Every day with every patient specimen, your laboratory has the power to change the course of that patient's life. It can be for the better if an accurate result aids the clinician in making a difficult diagnosis. But, it can be for the worse if the lab test result is inaccurate due to the lab's internal deficiencies and failures, thus misleading patient and doctor. Every lab professional knows how a single wrong lab test result can cause irreversible—and sometimes lifelong—harm to the patient.

It may not have occurred to you that your preferred source of lab news and analysis faces similar risks. You rely on your lab news provider to cover all the stories that are important. You trust your lab news source to get the facts right, and provide objective and unbiased reporting of these news events. Simply put, you want to trust your source of laboratory news just as patients and physicians want to trust the accuracy of the lab test results reported by your laboratory.

That is why it is important to you as a reader that THE DARK REPORT has won its second national journalism award for "Best Investigative Reporting." This is validation by an indendent panel of journalists that THE DARK REPORT is both covering the stories that are important to the laboratory industry and reporting them accurately.

I hope you will join me in congratulating editor Robert L. Michel and the entire team at THE DARK REPORT for this national recognition. It is a sign that there is a free and independent press reporting on the stories that are important to the laboratory testing profession. TDR

Healthcare Reform and Threats to Lab Testing

Laboratory testing industry will face threats from two primary aspects of health reform process

CEO SUMMARY: Annual healthcare spending now pushes past $2.5 trillion and this summer's debate about how to best reform healthcare in the United States will be raucous and emotional. For the laboratory testing industry, the stakes are immense. THE DARK REPORT identifies two primary threats to the lab testing profession. One is spending cuts to existing government lab testing programs to free cash for other purposes. The second is the potential for closed provider networks in new health programs.

By Robert L. Michel

IT IS THE DECLARED GOAL of the President and his party leaders in Congress that major healthcare reform legislation be passed this summer and a bill be ready for his signature before Labor Day.

This fact alone turns the upcoming lawmaking process into a high stakes game for pathologists, laboratory executives, and all laboratory professionals. That's because no option will be left unexplored. Congress needs to cut existing health spending programs to free up money it can then apply to its vision of a reformed healthcare system that brings the uninsured and under-insured into some form of health coverage.

Keep this in mind as you follow the lawmaking process during the remainder of the summer. On an **ABC News** interview earlier this month, Health and Human Services (HHS) Secretary Kathleen Sebelius stated "I think... he [President Obama] is very serious about having health reform this year and having it paid for." She later noted that cutting existing healthcare spending would be a source for funding the healthcare reform proposals, noting "...some of that saving [will come] from existing [health] programs that we've used to drive quality and expand coverage."

Lawmakers need to identify funds estimated at between $1 trillion and $1.8 trillion to pay for the basic health reform proposals already outlined in several proposed bills. That means no existing source of Medicare spending will avoid scrutiny, including the Medicare Part B laboratory test fee schedule.

In turn, that means the laboratory testing industry will face threats from two primary sources. First is the need to cut

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R. Lewis Dark, Founder & Publisher. Robert L. Michel, Editor.

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

spending on existing Medicare services to re-direct that money to the healthcare reform bill. The second is whether the master healthcare reform bill that eventually passes encourages market-based principles that allow all laboratories to compete vigorously for business—versus a healthcare reform bill that mandates closed provider networks in ways that restrict laboratories from serving any and all physicians and patients.

Cutting Medicare Spending

When it comes to spending cuts, pathologists and lab directors should have no misconceptions. Congress is going to pick through current Medicare spending programs with the proverbial fine-tooth comb. As an example, the early news is not good for radiology. Radical cuts to radiology and imaging services have already been openly proposed.

At some point, it will be the turn of anatomic pathology and clinical laboratory testing. What are the bad ideas that have dogged the lab testing profession since the advent of DRGs (diagnostic related groups) and similar Medicare program changes since 1983? Don't be surprised as they are trotted out again for consideration.

Will 20% Co-Pay Come Back?

Remember the 20% co-pay for Part B laboratory testing? Some congressperson will bring that up. How about an arbitrary one-time 10% to 30% cut to the entire existing Part B laboratory testing fee schedule? Expect a senator or representative to put forth that option as a way to free up several billions in current spending and divert it to some other new health spending program.

Of course, there is always the threat of competitive bidding for Medicare Part B laboratory testing services. For legislators, there is at least one drawback to this option. It would take several years to implement competitive bidding and begin to deliver the hoped-for savings—if such savings were to actually materialize at the projected level.

These are not off-the-wall speculations about how spending cuts are identified. They are based on long-established political practices within Congress. Most lab managers recall earlier in this decade, when the 20% co-pay was working its way into both Senate and House bills for Medicare funding authorization. That happened because it was believed Senator Charles Grassley (R-Iowa) wanted to increase Medicare funding for rural hospitals. Since any new Medicare spending had to be offset by comparable cuts elsewhere, his staff spotted the idea of a 20% lab test co-pay as one source to fund extra dollars to rural hospitals.

This is how the game is played and 2009 will not be different. Each proposed healthcare reform bill will be scored by government budgeting agencies as to the spending required to implement its health programs. Lawmakers know they will have to cut (rob) Peter in order to pay Paul.

Intense Lobbying Expected

Because health spending in the United States now approaches $2.5 trillion per year, the numbers are huge. That means each proposed spending cut gores the ox of some vested interest. In response, a myriad of economic interests will vigorously lobby senators and representatives. On one hand, these interests want to protect their turf and forestall legislation that would leave them net losers in any healthcare reform bill that passes.

On the other hand, these same interests have equally powerful motives to steer legislation in ways that favor their financial fortunes in the final legislation that passes and becomes law. The laboratory testing industry will be challenged to deliver a message to lawmakers that stands out against the lavishly-funded lobbying campaigns of the pharmaceutical firms, health insurance lobby, and medical device manufacturers.

The second major threat to the laboratory testing industry is whether the final

healthcare reform creates or supports forms of closed provider networks that effectively prevent all laboratories from unrestricted access to serving all physicians and patients.

For example, the administration has floated the idea of a government-run health insurance plan that would compete with private health insurance plans. Were such a plan to become reality, would it contract for laboratory testing on an exclusive basis? Or would it follow an "any willing provider" policy that allows any laboratory and pathology group to provide testing services to beneficiaries?

It is highly speculative to discuss such an outcome at this point. The legislative proposals known to the public at this moment are broad in outline and skimpy with details. Further, once specific proposals are made public, each will trigger a lobbying response by the vested healthcare interests that support or oppose specific points. Intense lobbying often results in significant changes to the final legislation which is passed.

Two Serious Threats To Labs

Importantly, whatever the path and whatever the process that is used to craft healthcare reform legislation this summer that passes Congress and is signed into law by the President, the laboratory testing industry will face serious threats to the status quo.

As noted above, one threat is deep funding cuts in the existing Medicare Part B Lab Testing program to steer those funds to other health reform goals. The other threat is that new forms of health coverage or insurance plans are created which rely on closed provider networks—thus excluding many or most of the nation's local laboratories and pathology groups from access to those patients and physicians.

Expect a boisterous debate this summer as senators and representatives are forced to reveal the details of how their bills cut spending in one area of healthcare and divert that money to the healthcare reform bill. With trillion of dollars involved, achieving successful healthcare reform will be a difficult process. TDR

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Massachusetts Health Reform: Is Anyone Paying Attention?

IT WAS BACK IN **2006** when Massachusetts enacted a much-ballyhooed universal health coverage plan. In the three years since then, the results have been mixed.

One admirer of the Massachussett health reform model is Senator Ted Kennedy (D-MA), who has included elements of the Bay State's health reform in the Senate bill he is drafting. Others in Obama's health reform team have praised many aspects of the Massachusetts program.

But it is a reform program where enrollment of the uninsured is below expectations and spending is exceeding projections. "It does not look like the Massachusetts plan has actually been successful at accomplishing what it set out to accomplish according to its proponents, if you want to judge it by their criteria," stated Michael Tanner, who is a Senior Fellow at the **Cato Institute** and author of the book, "Health Competition: What's Holding Back Health Care and How to Free It."

"The reality is that in 2007, the first year after the plan went into place, insurance premiums rose by 7.4 %," noted Tanner. "It went up by about 12% in 2008, and they're expected to rise 9% this year. Overall, that's an average of 10% to 12% increases in the insurance premiums in Massachusetts... That's compared to a 6% to 7% increase nationally over the same period."

Actual spending for the health program has consistently run ahead of state budget projections. In response, the Massachusetts legislature is scrambling to find sources of revenue to cover the cost overruns in the state's universal health program.

Lab Briefs

NEW PATHOLOGY LABS OPEN ON EAST COAST AND WEST COAST

TIMES MUST BE GOOD for anatomic pathology companies—at least two companies have each announced the opening of a new laboratory facility.

On the East Coast, it was **CBL Path, Inc.**, of Rye Brook, New York, which expanded. On May 29, it announced the opening of its new laboratory in Manhattan, located on East 66th Street. Because this is pricey real estate, it is likely that CBL Path's strategy is to offer faster turn-around times for its client physicians in Manhattan.

On the West Coast, it was **Plus Diagnostics, Inc.**, which opened a new laboratory facility in Laguna Hills, California, a city in Orange County. The new laboratory was opened in April. Plus Diagnostics is also building a new laboratory in Union, New Jersey. It plans to take occupancy in August 2009. Plus Diagnostics was formerly known as **Lakewood Pathology Associates**. It changed its name in 2008.

For both CBL Path and Plus Diagnostics to open new laboratories is one sign that demand for anatomic pathology testing—especially in the urology and gastroenterology specialties served by both companies—continues to be strong, despite the current economic recession.

NEW TECHNOLOGY ENABLES WESTERN BLOT BY DIGITAL IMAGING

RESEARCHERS ARE APPLYING NEW TECHNOLOGY to the long-established Western Blot process. They hope to produce a methodology that produces more quantifiable data and more reproducible data.

Currently, chemiluminescence is in common use. It generates a low-light signal and is typically reproduced by film. Uneven stripping of the blot can sometimes cause loss of quantitative information. Use of fluorescently-labeled secondary antibodies is another recent approach for these assays.

Enter the Western Blot by digital imaging. Two developments support this new approach. First, charge-coupled device (CCD) camera technology has improved in ways that support its use in Western Blot testing. Second, chemiluminescent substrates optimized for digital imaging have recently become available. For example, **Alpha Innotech Corporation** of San Leandro, California, sells such a product, which it calls ChemiGlow. Initially, the primary market is expected to be pharmaceutical researchers.

Scientists are demonstrating that digital imaging provides a greater linear dynamic range when used for Western Blots. By replacing film, digital imaging generates a number of benefits in conducting the test and evaluating the results.

This new technology and its application in Western Blot testing demonstrates how improvements in different technologies can be combined to create a new diagnostic methodology. It is also a reminder of how quickly digital imaging capabilities are improving.

DNA DIRECT TO ADMINISTER HUMANA'S GENETIC TESTING

ORGANIZED TO SERVE the genetic testing needs of consumers, **DNA Direct** of San Francisco, California, has added an important new customer. Effective this summer, it will handle preauthorization and notification of molecular diagnostic testing and genetic testing for **Humana, Inc.** This arrangement plays to DNA Direct's core competencies in counseling consumers about genetic testing. It also is an example of a new competitor to clinical labs. TDR

New Phlebotomist Policy Achieves Zero Error Rate

For more than a year, Nevada medical center cuts contaminants in blood cultures to zero

CEO SUMMARY: It's not often when a hospital laboratory can use a patient safety project to achieve zero defects for more than one year. But that's what happened at Desert View Hospital in Las Vegas, Nevada, when it went an entire year with no contaminants in draws for blood culture. DVH has 25 beds and does 110 blood culture draws each month. Nationally, the average rate of blood culture contamination is 3% to 5%. The financial benefits to the hospital supported the cost of adding more phlebotomy staff to achieve this goal.

ACHIEVING A ZERO RATE of contaminated blood cultures for more than a year by taking simple management steps is the lesson to be drawn from the experience of the laboratory at **Desert View Hospital** (DVH) in Pahrump Valley, Nevada.

This achievement saved the hospital $252,000 in the first year alone, based on savings calculated from the national average of contaminated blood cultures. It came about because of a management emphasis on how phlebotomy duties were performed.

"During 2007, our hospital had a rash of contaminants in blood cultures that caused us to exceed the national average of 3% to 5%," recalled Henry Pfiester, Laboratory Manager at DVH. "The majority came from nurse draws and others were from phlebotomist collections.

"To address this problem, in January 2008, we retrained all phlebotomists in the proper methods of collecting blood cultures," he explained. "A policy was then implemented that only phlebotomists could draw blood culture samples. In the first few months, we had a few contaminated cultures. But then the number fell to zero and our blood cultures have been contamination-free since April 1, 2008. It was as simple as that!

Cost-Benefit Analysis

"In other places where I've worked, I've seen the same thing: high rates of contaminated blood cultures," Pfiester commented. "But unfortunately, in some facilities, hospital administrators are reluctant to do anything about it because it would cost money to hire phlebotomists.

"But that is false economy. When you consider that one contaminated blood sample can cost a hospital $3,000 or more per contaminant, some hospital administrators are often penny wise and pound foolish when they decline to spend the money to hire phlebotomists to collect samples the proper way.

"In doing a blood culture, for example, if the person drawing the sample coughs or sneezes when drawing the collection, then normal flora from the throat have been introduced into that culture," noted Pfiester. "When these blood cultures are

incubated, they come up positive or negative. If positive, the lab doesn't know what caused that positivity. Thus, the patient cannot be released from the hospital until that positive result is identified. If it's a pathogenic organism, the patient needs to be treated immediately with an antibiotic.

Hospital Bears Cost of Errors

"But if it's a contaminant, which is often a normal skin flora or normal throat flora, then the patient cannot be charged for their extra stay," he added. "They can't be released and so the hospital bears the cost of keeping them for an extra day until that contaminant is identified. The national average for a day in a hospital is $3,000—and that's just for a normal hospital day! It can be three or four times more for a specialized hospital day.

"Ten cases at $3,000 each adds up to enough to hire a phlebotomist at $11 per hour for 40 hours a week," observed Pfiester. "In our hospital, we have only 25 beds and do only 100 to 150 blood cultures a month. If we have even the national average of contaminants of 3% to 5%, that would be 3 to 7 patients a month. That's $9,000 to $21,000 in extra costs each month. Yet, the cost of an extra phlebotomist is much less than that. Depending on experience, a phlebotomist will get paid $11 to $15 per hour.

"In our first efforts to lower rates of contaminated blood cultures, we tried training the nurses to do the blood culture draws properly," he said. "That didn't work because, like everyone else in the hospital, nurses are short staffed. When lots of patients present in the emergency room, nurses don't have time for the niceties.

Phlebotomists Draw Blood

"So our next step was to hire an extra phlebotomist to do blood culture draws during the day, the time when most cultures are drawn," Pfiester explained. "If a blood culture needs to be done at night, then it is our policy to have a phlebotomist draw that sample. That change in policy costs nothing, while the additional day phlebotomist increases our staff costs by $11 to $15 an hour for eight hours five days a week.

"We considered this to be a no-brainer investment," he said. "Of course, there is always the hospital administrator who, upon hearing this type of proposal, may give it a thumbs down because it means the hospital will be hiring another phlebotomist. They want to avoid adding to the number of staff.

Focusing on Cost Control

"Our success in this regard came because we presented a cost-benefit analysis and it made sense to our administration," noted Pfiester said. "At other hospitals, administrators might simply want to keep head count down or it could be that the financial incentives are not aligned properly. In some cases, there may be outside managers or contractors involved and who veto the proposal.

"At our hospital, everyone shares in the cost of hiring the phlebotomist because the lab at DVH is run by the hospital and not by an outside agency," he added.

"Even though we have a small hospital, the costs of a contaminated blood culture can add up quickly at $3,000 per case," Pfiester explained. "Last year we did about 250,000 billed tests. We have six full-time technologists, two per-diem technologists, six full-time phlebotomists, and two per-diem phlebotomists. For pathology services, we hire a pathologist from **Quest Diagnostics Incorporated** and he serves as our medical director."

THE DARK REPORT observes that health care policy experts have a significant challenge in uncovering all of the examples where misaligned financial incentives can thwart the best efforts to control spending. Fortunately for DVH, the financial incentives are aligned properly so that the medical center can cut costs effectively.

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DARK REPORT and Editor Michel Earn National Reporting Award

News association bestows "Best Investigative Reporting" for coverage of unprecedented Vitamin D test inaccuracies

FOR THE SECOND TIME in recent years, Editor Robert L. Michel and THE DARK REPORT have won a national award for "Best Investigative Reporting."

In Washington, DC, last month, at the **Specialized Information Publishers Association** (SIPA) annual conference, Editor Michel learned that judges had bestowed the First Place award for "Best Investigative Reporting" to THE DARK REPORT. The award was for its coverage of the unprecedented disclosure by **Quest Diagnostics Incorporated** that, for an 18-month period in 2007 and 2008, deficiencies in its home brew, tandem mass spectrometry Vitamin 25(OH) D testing program had caused it to report inaccurate results to what is estimated to be hundreds of thousands of patients.

At the Specialized Information Publishers Association Conference in Washington, DC, NBC Anchor Nora O'Donnell (r) presented DARK REPORT Editor Robert Michel (l) with the First Place Award for "Best Investigative Reporting."

This news story, first published in the December 22, 2008 issue of THE DARK REPORT, was picked up by the *New York Times, ABC's Good Morning America*, and other national news outlets. It startled the public to learn that a respected laboratory company in this country had reported inaccurate lab test results for such an extended period of time. *(See TDRs, December 22, 2008, January 12, 2009, and February 2, 2009.)*

This prestigious national award for best investigative reporting is the second time that THE DARK REPORT and Michel have won such an award. In 2005, SIPA (then called the Newsletter and Electronic Publishers Association) Awarded THE DARK REPORT a "Best Investigative Reporting" award for its extensive investigation into anatomic pathology laboratory condominiums (pod labs) during 2004.

THE DARK REPORT'S exhaustive, detailed investigation into how urologists had created this AP condo business model and were selling it to other physicians is credited with attracting the attention of federal health regulators, who issued an unfavorable opinion letter on this business model in December 2004.

With this second journalism award, THE DARK REPORT continues to be the only news and business intelligence source in the lab testing industry to have earned such recognition at the national level. In turn, this is important validation for clients and regular readers that THE DARK REPORT is respected by other journalists for the quality and integrity of its reporting of lab industry news. TDR

CEO Summary: Biophysical Corporation is creating a new, direct-to-consumer market for laboratory testing. Its unique approach is to offer 250-bioassay test panels—along with a staff physician review of results—to the educated, informed consumer. Testing multiple biomarkers makes it possible to identify disease and predict risk in asymptomatic patients. High profile customers such as Oprah Winfrey and Martha Stewart have discussed their positive experiences with this testing in television interviews.

Biophysical Corporation of Austin, Texas, Enjoys Growing Market

Educated Consumers Buying 250-Bioassay Lab Test Panel

LISTENING TO THE VOICE OF THE CUSTOMER led to the creation of an intriguing new business model for laboratory testing by **Biophysical Corporation**, based in Austin, Texas.

For the past four years, Biophysical has marketed a 250-assay test panel directly to consumers. Called the Biophysical250, it is more than a wellness panel and is specifically designed to accurately diagnose disease in an asymptomatic patient.

On both these counts, Biophysical is blazing a new path for the laboratory medicine profession. First, it is demonstrating how a well-designed, extensive panel of laboratory tests can detect disease and other health conditions that have gone unobserved by the consumers' healthcare providers.

Second, it is serving a group of consumers that proactively monitor their health. These individuals have both the education and the financial resources to intelligently watch their health and pay for any medical services that maximize their health and well-being.

Of note to the wider lab testing industry, the Biophysical250 test panel has earned plaudits from such well-known individuals as Oprah Winfrey and Martha Stewart. Both women have discussed their Biophysical250 lab test experience in television interviews.

In fact, the Biophysical250 has been discussed on five different Oprah shows. Oprah even told her television audience that the Biophysical250 laboratory test panel was such an important window on an individual's health status that she was giving this $3,400 comprehensive testing panel to her friends as a gift!

Biophysical's new laboratory testing business model is based on unique diagnostic technology familiar to many lab managers and pathologists. It is the xMap multi-analyte bioassay system developed at **Luminex Corporation** by founder and former CEO, Mark Chandler, Ph.D., during the 1990s.

In 2002, Chandler saw how xMAP could be a tool to help the pharmaceutical industry identify, in advance, which patients would have an adverse response to new drugs. This innovative molecular technology, which he invented in collaboration with his brother, Van Chandler, analyzes 100 unique biomarkers using just a single drop of blood.

➤100 Assays Per Specimen

"It gives drug developers a cost-effective way to predict drug toxicity," stated Chandler. "It uses small quantities of specimen and reagent, provides a quick, reliable answer, delivers high sensitivity and specificity, and allows the drug developer to perform up to 100 assays per specimen simultaneously."

Back in 2002, the problems with prescription drugs Rezulin and Baycol were still fresh in the minds of all drug developers. Makers of these drugs were forced to pull them from the market shortly after FDA approval, when some patients experienced severe adverse effects or death. "I recognized how xMAP technology could be used to provide toxicity testing services to pharmaceutical companies," recalled Chandler. "That same year, we established **Rules Based Medicine, Inc.** (RBM), a biomarker-testing laboratory facility, to offer this service to the pharmaceutical industry."

The story now takes a fascinating twist that leads directly to the creation of Biophysical Corporation in 2004. "The idea for the Biophysical250 lab test panel evolved out of the technology's ability to accurately diagnose a disease in an asymptomatic patient, often years before it's found by other means," he said.

"As pharma companies began using RBM to screen candidates for clinical trials, something very unexpected happened," he stated. "Both research scientists conducting the clinical studies and pharma executives began sending specimens of their own blood for analysis, along with blood samples from trial participants! They wanted to know if they had any undetected diseases or sinister biomarker combinations that predisposed them to a disease.

"We quickly realized that, if these scientists were using our multi-assay test panels

to evaluate their own health status, this diagnostic service would have appeal for others in the healthcare community," he added. "It was August 2005 when Biophysical Corporation launched the Biophysical250 lab testing panel."

Expanding Consumer Trend

Chandler is quick to point out that the concept of proactively testing an asymptomatic individual to accurately diagnose previously undetected disease meets the need for a growing number of consumers in this country. "Since the millennium in 2000, consumer interest in proactive medicine, personalized healthcare, and preventive products and services has increased at a steady rate," observed Chandler.

"In this decade, integrative medicine has become mainstream and a variety of consumer-oriented products and services have emerged in response to consumer demand," he commented. "Laboratory professionals have watched consumers support things like patient self-test devices, the full-body MRI, personalized medicine, bio-identical hormone replacement, and other anti-aging therapies.

"It is consumer support which has fueled the strong growth in 'boutique' or 'concierge medicine' in recent years," said Chandler. "These are all examples of personalized healthcare services focused on wellness, rather than illness—supported by the willingness of financially better off individuals to pay extra to get these services.

"For example, in a concierge medicine setting, patients pay their doctors an annual retainer of $1,200 to $25,000 to receive premium healthcare services," he noted. "The concierge physician provides them with house calls, a comprehensive physical, access to a doctor day or night, extended office visits, and other services not covered by insurance.

"We designed the Biophysical250 and our related test panels specifically to serve consumers who are informed, involved in managing their health, and keenly interested in understanding their risk factors for a variety of diseases," explained Chandler. "These are motivated individuals—different from the traditional patient who typically only visits the doctor when he/she feels bad.

"In fact, if you believe that the future of healthcare is preventive medicine and personalized medicine, then the Biophysical250 test panel now serves that first wave of informed, educated consumers who are acting proactively to forestall disease and maintain their health at peak levels," observed Chandler. "Like the clinical trials scientists who sent in their own blood, these consumers are taking active steps—and spending their own money—to optimize their personal health."

Having explained how Biophysical, Inc., came into existence and the profile of the consumers and patients it serves, pathologists and laboratory administrators will be interested to learn more about the design of the Biophysical250 lab test profile and how it is used by consumers and their physicians.

Simple Concept For Testing

"The concept is simple," explained Randy Marfin, Vice President of Sales and Marketing for Biophysical Corporation. "The Biophysical test panel combines all known biomarkers that define specific medical conditions or diseases into a single, relatively inexpensive test panel.

"The xMap technology we use is the secret behind the Biophysical250," he continued. "First, because it uses tiny amounts of specimen per assay, we typically need to collect only three red top (8.5 mil) tubes and two purple top tubes (4 mil) from the patient. By contrast, drawing the quantity of blood needed to run 250 individual assays using traditional laboratory testing methods would be impossible without killing the patient.

"Second, the economics of xMap technology are favorable for this application," Marfin said. "If a patient was to go to a clinical laboratory and order the same 256 biomarkers in the Biophysical250, it would cost

about $40,000, compared to the $3,400 cost of the Biophysical250 test panel.

"Recognizing that consumers have different needs, Biophysical Corporation offers seven different panels of tests," continued Marfin. "For example, Biophysical CA/CV is designed for people who want to enhance their personal health surveillance program for cancer and cardiovascular disease. It uses multiple biomarkers, supported by clinical studies, that collectively deliver high sensitivity and specificity compared to a single biomarker.

Test Is In Best-Selling Book

"In the best-selling book *YOU: Staying Young*, authors Michael Roizen, M.D., and Mehmet Oz, M.D., discuss how factors like exercise and nutrition play a role in health. At their request, we created the 'Biophysical You' test panel to include specific biomarkers discussed in this book.

"Our seven test panels meet specific needs for different consumers," he commented. "Each test in the seven panels looks for biomarkers associated with specific diseases, conditions, or bodily functions. Each test panel varies in price according to the number of biomarkers analyzed, from as little $475 for Biophysical CA/CV, which checks for cancers and cardiovascular disease, up to $3,400 for the Biophysical250—the full works."

"Biophysical is a consumer-driven model, selling directly to consumers willing to invest in their health," explained Chandler, noting that Biophysical test panels have done particularly well with consumers living in South Florida. "Thanks to the Internet, today's healthcare consumer is more informed than ever, which is why the market for wellness-oriented products and services is booming.

"The consumer-driven health market is growing unbelievably fast," he added. "Consumers want to make use of advances in medical science. And they also don't want their health determined or limited by what insurance will or will not pay."

Biophysical Test Panel Has Robust Lab Technology

FOR MORE THAN A DECADE, laboratories have been able to use the same combination of simple, robust technologies that make up the Biophysical250 laboratory test panel.

Biophysical's technology is the xMAP system licensed from Luminex Corporation. It starts with microbeads impregnated with precise proportions of two fluorescent dyes in 10 different intensities to create a set of 100 unique microspheres. Every bead set has its own color-coded spectral address.

Each bead set is then coated with an immunochemical reagent specific to a particular bioassay that binds with the specific biomarkers of interest in the blood sample.

Using a proprietary analyzer consisting of sophisticated lasers, state-of-the-art digital signal processors and a fluidic process similar to that used in flow cytometry, patient samples are analyzed and results reported in real time. As beads flow through the optic chamber, one laser excites the internal dyes and classifies which biomarker is being tested. The other laser excites the external reporter dyes and quantifies the amount of biomarker present in the sample.

The testing process is fast, highly sensitive and specific, and uses minimal amounts of specimen and reagent—compared to conventional diagnostic technologies.

Marfin points out that biomarker testing presents an opportunity to dramatically cut healthcare costs. "These test panels combine all biomarkers that help define a specific medical condition into a single, low-cost test, which enables the physician to quickly create the most accurate picture of a patient's health.

"Take diabetes," continued Marfin. "This is an expensive problem. The **American Diabetes Association** estimates that a diabetes patient costs the healthcare system an extra $6,650 per year. In the vast majority of cases, Type II diabetes can be prevented or

postponed with diet and exercise. Here is where biomarker panels have value. Early detection is critical for a successful intervention program and glucose testing alone may not be adequate to help physicians identify high-risk patients that are in a pre-diabetic condition. A physician must look at all the relevant biomarkers to identify those patients who are pre-diabetic. Once identified, those patients can make the lifestyle changes required to prevent diabetes."

Another way that Biophysical's test panels contribute to better use of healthcare resources is as a screening tool to determine which individuals are candidates for more expensive imaging procedures. "Mammography is an example," said Chandler. "Although it is among the most trusted of imaging tests, it produces false-positives 95% of time.

"We predict a convergence of imaging and biochemical diagnostics will take place as a way to end wasteful or unnecessary imaging procedures," he explained. "Doctors will order cost-effective, multi-assay biomarker screening tests first, then follow up—when indicated—with more expensive imaging procedures that provide greater details about the patient's condition."

More Consumer Awareness

In its early years, Biophysical built its business by focusing on the informed consumer and using public relations activities. Greatly expanded consumer awareness of the company's testing services resulted from mention of the Biophysical250 in the best-selling book *YOU: Staying Young*, along with attention generated by the television interviews of Oprah Winfrey and Martha Stewart.

Now Biophysical Corporation is marketing itself to physicians who have organized their medical practice to serve the educated and proactive patient. "We want to turn actionable knowledge generated by the Biophysical250 over to doctors who can determine and start appropriate treatments," noted Marfin. "We find that physicians with a concierge practice or boutique component actively promote preventive medicine and they are quick to see the benefits of the Biophysical250 for their patients."

Both Chandler and Marfin believe biomarker testing will one-day be a routine part of everyone's health care. "When this happens, pathologists will need to operate more like radiologists," predicted Marfin, who noted that radiologists are skilled at offering a course of treatment along with radiology reports.

Physician Review Of Results

"In fact, part of every Biophysical250 is a review of the results by our staff physicians with both the referring doctor and the consumer," explained Marfin. "These reviews can take more than an hour, depending on the findings for an individual patient. As a laboratory testing resource, we recognize how important it is for referring physician and the consumer to fully understand the information produced by these sets of biomarkers and what medical actions and lifestyle changes are indicated. We insist that our staff physicians have a direct role in communicating the findings."

Off the radar screen of the laboratory testing industry, Biophysical Corporation has quietly been creating a new laboratory testing business model. Because it is oriented to serve preventive medicine and personalized medicine, it provides pathologists with an interesting window into laboratory medicine's future.

That future promises an active, consultative role for pathologists. "As more consumers demand more sophisticated lab testing services, pathologists will have an opportunity to partner with those physicians practicing personalized medicine," Marfin concluded. "This consulting relationship will work because pathologists will be giving actionable information and treatment recommendations based on an evaluation of multiple biomarkers." TDR

—P.Kirk

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Preventive and Personalized Medicine Goals Served by Biophysical250 Lab Test Panel

CUSTOMERS OF BIOPHYSICAL CORPORATION typically fall into two categories. One category is made up of consumers who are proactively managing their health. The second category consists of physicians who are incorporating the seven Biophysical test panels into their medical practice.

The value of these test panels in early detection of disease is demonstrated by many stories. Rick Nagel, CEO of Oklahoma City-based **Acorn Ventures**, was so impressed with Biophysical250 he purchased it for himself and his entire management team. Nagel learned about the test from his wife, whom had suffered from pain in her abdomen until Biophysical helped correctly diagnose her problem, after which she was properly treated.

"I looked at it [the cost] as a worthwhile investment in our management team," Nagel said, noting that he was glad to pay for the baseline knowledge, but then it is the responsibility of each executive to work on risk factors and follow-up with specific testing. "A couple [of executives] had cardiac issues and needed to change behaviors. But at the macro level, I was pleased to learn that our management team has a good health baseline."

Integrated Medicine

Among physicians, Paul Rothwell, M.D., is a first-mover in Integrative Medicine. He established a wellness component to his regular family practice in Bethany, Oklahoma. "I wanted to provide private-pay patients with the latest evidenced-based anti-aging treatments shown to provide optimum health," stated Rothwell.

He offers Biophysical laboratory test panels through his anti-aging, regenerative medicine, consumer-oriented practice, **Wellness and Longevity, LLC**. This specialty practice evaluates patients through physical examination and targeted laboratory studies to identify potential problems and deficiencies. The information is used to develop a plan to get the body back in balance, which might include supplements, bioidentical hormone therapy, and nutritional counseling.

Rothwell learned about Biophysical when one of his patients showed up for an appointment with his Biophysical test report booklet. "At first, I was surprised by the expense, but then I saw how comprehensive it was," he said. "We spent an hour together looking it his results.

Patient Wanted Testing

"This patient decided to have the Biophysical test panel after his brother suffered a heart attack," recalled Rothwell. "He was in his early 50s and had no symptoms of cardiac issues. The Biophysical results indicated that his vital numbers were perfect, but did indicate the need for imaging tests that I may not have otherwise ordered for this patient."

Discussing his personalized medicine practice, Rothwell said the specialty practice allows him to go beyond insurance limits to proactively manage a patient's health. "For instance, insurance companies may cover a TSH test to screen for thyroid disorder," he noted. "But an entire thyroid profile is often required to make a good medical decision.

"They taught us in medical school to be reactive and treat diseases. But in treating the masses, if we approach medical care proactively, rather than reactively, healthcare costs would come down," emphasized Rothwell. "Comprehensive biomarker testing like the Biophysical panels is the future of medicine."

Teamwork Between Labs Helped NYC Flu Response

City's public health laboratory worked closely with hospital labs to handle A/Novel H1N1 testing

CEO SUMMARY: Shaped by the experiences of 9/11 and the anthrax outbreak in 2001, the New York City Department of Health and Mental Hygiene revised and improved its preparedness plan. With the outbreak of influenza A/Novel H1N1 this spring, the Public Health Department benefited from effective collaboration with area hospitals and commercial laboratories. The public health laboratory, although testing as many flu specimens in a day as it typically tests during one year, kept pace with the incoming sample flow and provided timely results to health officials.

WHEN CLINICAL LABORATORIES WANT to assess the lessons learned from the recent outbreak of A/Novel H1N1 influenza, a good starting point is New York City, for two reasons.

One, it was among the first regions in the United States to confirm positive cases of A/Novel H1N1. Two, as a densely-populated urban environment and transportation hub, its experience in responding to these types of outbreaks offers many useful insights. In particular, the collaboration between the **New York City Health Department** and the city's hospitals and commercial labs during the A/Novel H1N1 outbreak was quite effective.

"New York City certainly is a place in which congregate settings are a way of life," explained Sara T. Beatrice, Ph.D., the Laboratory Director and Assistant Commissioner of the city's Department of Health. "A large percentage of people commute on buses and subways and live in multi-dwelling housing units. Our citizens recreate in smaller areas with more people involved to higher degree than most other cities.

"We have a detailed pandemic influenza preparedness plan," she added. "It calls for a highly organized system of outreach between the Department of Health and the medical community, the city's hospitals, and commercial laboratories.

"Accordingly, while our public health laboratory experienced a much higher level of testing demand for A/Novel H1N1 during the outbreak, we also had a level of samples that we could manage," said Beatrice. "We believe our preparedness plan played a role in containing the level of samples we tested.

Surveillance Testing

"Based on our experience with similar outbreaks, we have learned that when a new cluster is identified, the number of samples taken should be the minimal number to indicate that it is or is not a true cluster," Beatrice noted. "In this way, our approach was unlike that of many parts of the country—where anyone who presented had a sample collected and tested. Our approach is to have much more focused testing.

"It is important that the response plan evolves over the course of an event, meaning the questions that we want to answer at the very beginning may be different than the questions that we want answered two weeks later," continued Beatrice. "In New York City, the first question to answer was: Is the pathogen here? The next questions are: Is it in a congregate setting? Is it severe? Is there community transmission?

Lessons Learned from 9/11

"Our experience with anthrax in New York City in 2001 taught us the importance of reducing the wave of samples that can swamp the public health laboratory," stated Beatrice. "The anthrax event generated a huge number of samples from individuals who had no probable cause. When that happened, the anthrax-tainted letters that had been sent to NBC News and ABC News were stuck in the middle of that massive deluge of inappropriate submissions that came into our lab.

"That experience taught us that it actually takes longer to answer the important questions and to get the testing done on the critical samples when you test every sample," she said. "That's why, despite the pressures from the emergence of A/Novel H1N1, the people involved in this event could stay focused and perform the testing at an appropriate and manageable level.

Cooperation Required

"In order to do as well as we did, we had to have good cooperation from hospital labs and we got that cooperation because we have an excellent network of sentinel labs here," observed Beatrice. "This was a lesson we learned after 9/11 and the anthrax outbreak. There was a clear need to strengthen the relationship between the public health laboratories, hospitals, and commercial laboratories.

"Each year we offer different types of training and outreach to hospitals and laboratories," added Beatrice. "We know all the lab directors and supervisors. During the A/Novel H1N1 outbreak, those established relationships made it easier for us to set up conference calls with various hospital labs to review how best to collect and transport flu samples to the health department."

That communication was an important part of the success of the outreach between the city Health Department and the hospitals and commercial labs. The Bureau of Communicable Diseases had daily conference calls with the hospitals in all five boroughs.

This response was appropriate given that the worried well were streaming into

New York City Experienced A/H1N1 Cases and Deaths

TO DETERMINE THE LEVEL OF flu illness in New York City, the Health Department conducted a household survey in the first three weeks of May. The survey results showed that some 6.9% of New Yorkers experienced flu-like illness between May 1 and May 20. "The findings don't tell us exactly how many New Yorkers have had A/Novel H1N1 influenza," said Health Commissioner Thomas Farley, M.D. "But they suggest it has been widespread, and mild in most affected people."

Since late April, 804 New Yorkers have been hospitalized with A/Novel H1N1 flu, and 32 deaths have been linked to the virus. Even with the survey, it was not clear what proportion of residents with flu-like illness had the A/Novel H1N1 virus, but the evidence suggested that A/H1N1 has spread widely in the city, Farley said. In fact, the peak period of A/Novel H1N1 activity may have occurred after the survey was completed.

As reported by the **Centers for Disease Control and Prevention** (CDC), through Friday, June 26, there have been 27,717 confirmed cases of A/Novel H1N1 influenza and 127 deaths in the United States. Confirmed A/Novel H1N1 cases have been reported in all 50 states, plus Puerto Rico and the U.S. Virgin Islands.

hospital emergency departments in large numbers. Daily interaction with hospitals to review protocols helped the public health labs meet this demand.

"This was also the channel we used to craft the public information message," said Beatrice. "The worried well needed to know what to do and what not to do. With most mild cases of the flu, the appropriate thing is to stay home and not go to an emergency department and spread that virus further.

"Our heaviest test volumes for A/Novel H1N1 were between April 21 and June 19," Beatrice recalled. "The level of testing for that period peaked at about 100 A/Novel H1N1 tests a day when normally we run about 100 flu tests a year.

"During this event, our flu laboratory was dedicated to looking at clusters in congregate settings, such as schools and in hospitalized cases that met the case definitions," she noted. "The number of samples that we tested was small in part because of the frontline testing performed by hospital labs and commercial labs.

Lab Surveillance System

"Initial discussions about A/Novel H1N1 began when we saw what was happening in Mexico, California, and Texas during the week of April 20," Beatrice stated. "We initiated an active lab surveillance system through our Bureau of Communicable Disease outreach with numerous hospital laboratories in the five boroughs. The outreach goal was to communicate that, when hospital labs had cases of individuals who were ill and had tested positive on the rapid assay for influenza A, we wanted to receive those specimens so that we could test them for potential subtyping.

"Those first samples came in the evening of Friday, April 24," Beatrice continued. "At the same time our first cluster was occurring at a high school in Queens, where a large number of students presented with flu-like illness. A batch of those samples arrived that same evening. Lab staff, who had already worked their full week, stayed over to test these specimens. They didn't finish and leave the lab until 2 a.m. on that Saturday, April 25.

"From that day forward, it was a very heavy schedule for about two months," she added. "We worked seven days a week, starting as early as 6 a.m. and finishing at 2 a.m. the next morning. It is only now beginning to slow down.

Seeing Spikes in Demand

"Demand for influenza testing was heavy for the first two weeks and then after the first couple of weeks, there was a slowdown, which is what happens if you look at a transmission graph," she said. "For one or two weeks, we had no weekend work. But then the samples started rolling in again and we worked weekends up until about the middle of June. Over the weekend of June 20 and 21 we did not work and the weekend of June 13 and 14, we worked on Saturday but not Sunday. That workload shows that A/Novel H1N1 was a more protracted event here than it might have been elsewhere.

"Our public health laboratory is staffed with about 200 people. A team of 40 people performed A/Novel H1N1 testing. They were rotated on a seven-day schedule," Beatrice said. "Some did testing. Some triaged samples and some worked the databases. Others prepared summary reports to help us push out information to various parts of the city government, along with the hospitals and doctors."

The speedy and effective response of public health officials to the outbreak of A/Novel H1N1 in New York City required effective collaboration with hospital laboratories and commercial labs in the region. Because of prior planning and education, the New York City public health laboratory was able to stay up with the incoming flow of influenza specimens that required testing. TDR

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INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

In recent weeks, the laboratory at **Blanchard Valley Hospital** in Findlay, Ohio, received its accreditation for ISO 15189: Medical Laboratories. With this achievement, Blanchard Valley becomes only the third lab in the United States to become ISO 15189-accredited. Blanchard Valley's laboratory used the ISO 15189 accreditation services provided by the **College of American Pathologists** (CAP).

MORE ON: ISO 15189

ISO 15189 is still a new development in this country. It was only November 2008 when **Piedmont Medical Laboratory** of Winchester, Virginia, became the first U.S. laboratory to be accredited under ISO 15189. Then, 60 days later, in January 2009, the laboratory at **Avera McKennan Hospital** in Sioux Falls, South Dakota, received its 15189 accreditation. At the upcoming *Lab Quality Confab* on September 28-29, 2009 in Atlanta, Georgia, lab leaders from both Blanchard Valley Hospital and Piedmont Medical Laboratory will give presentations on the lessons learned and the benefits realized from their labs' ISO 15189 accreditation.

LUMINEX RELEASES 500-ANALYTE SYSTEM FOR MULTIPLEX TEST

Here's an interesting milestone of the road to multiplex diagnostics testing. On June 15, **Luminex Corporation** released for sale its enhanced Flexmap 3D system, a high-throughput multiplexing instrument that can simultaneously perform 500 tests on a single sample! This greatly increases the capabilities of its technology, which previously performed 100 analytes simultaneously on a single specimen. The Austin, Texas-based company says that the Flexmap 3D system is designed for use in medium and high-volume laboratories. It says the system can perform multiplexed genomic, transcriptomic, and proteomic biomarker analysis on a single platform.

ARUP CELEBRATES 25TH ANNIVERSARY

Over in Salt Lake City, Utah, on June 19, **ARUP Laboratories** celebrated 25 years in business. Founded in 1984, ARUP has posted steady growth. THE DARK REPORT congratulates the team at ARUP for two and a half decades of service, along with its contributions to the field of laboratory medicine.

TRANSITIONS

• In May, Margaret Peck, M.S., MT (ASCP) resigned her position as Executive Director of the Laboratory Accreditation Program at **The Joint Commission**.

DARK Daily
Clinical Laboratory and Pathology News/Trends

DARK DAILY UPDATE

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

...a new federally-funded study to determine if Vitamin D supplements and fish oil can reduce health risk. It will involve 20,000 people and be conducted by **Harvard Medical School**.

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, July 20, 2009.