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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 2

Commentary & Opinion by...

R. Lewis Dark

Founder & Publisher

Opening Pandora's Box

OUR EDITOR ONCE AGAIN HAS ANOTHER REMARKABLE PREDICTION for the clinical laboratory industry. In this issue, he predicts new point-of-care (POC) technology for routine chemistry and hematology testing will start the long-foretold process of laboratory decentralization. This follows on the heels of the last issue of THE DARK REPORT, when he predicted that web-based lab test ordering/results reporting is about to become the preferred communications vehicle between clinical labs and physicians' offices, in two years or less!

I had to take him to task on his newest prediction about the influence of point-of-care technology on centralized laboratories. After all, as you will read on pages 2-14, **CARESIDE, Inc.**'s new point-of-care instruments for routine, high-volume chemistry and hematology tests are not yet available in the market, although that will change in the coming weeks.

Robert Michel, our editor defends his prediction with an interesting argument. He calls it the "Pandora's Box Paradox." In simplest terms, if CARESIDE's new point-of-care chemistry analyzer is cost-competitive with routine chemistry tests now done in centralized core laboratories, then it will begin to nibble at the market share held by the big chemistry instrument vendors. You all know the names—**Roche**, **Abbott**, **Beckman-Coulter**, **Ortho-Clinical Diagnostics**, **Bayer**.

Editor Michel says that these diagnostic powerhouses are not going to let start-up companies like CARESIDE erode their market shares. These companies will defend their business by developing their own point-of-care solutions for high-volume, routine chemistry testing. Thus, CARESIDE's launch of its new POC instrument suite is like opening Pandora's Box. Like it or not, once the box is open, mischief is let loose on the world.

For my part, I argue that it is difficult for billion-dollar diagnostic companies to take CARESIDE seriously, particularly when its products have yet to demonstrate their performance in actual clinical use. Editor Michel has an interesting rebuttal. He points out that it took CARESIDE only 36 months and about $20 million to take existing state-of-the-art chemistry and hematology technology, and create a viable point-of-care instrument solution. He says that's chump change for a billion-dollar company. Once they get serious, they can develop their own POC product—and fast! I guess if that happens, then CARESIDE really did open Pandora's Box. TDR

Point-Of-Care Chemistry Ready To Transform Labs

This POC instrument suite offers a new value-added proposition for lab medicine

By Robert L. Michel

CEO SUMMARY: Following on the heels of our prediction about web-based test ordering/results reporting, here's another equally revolutionary development. CARESIDE, Inc. is ready to launch a point-of-care instrument suite for routine, high-volume chemistry and hematology tests. Early peeks at this technology reveal its potential to revamp the organization of both hospital and commercial laboratories.

WITH THE NEW MILLENNIUM comes innovative point-of-care technology which will decentralize laboratories and change the way clinical labs are currently organized and operated.

The technology is **CARESIDE, Inc.**'s revolutionary system for doing point-of-care (POC) chemistry and hematology tests. The company is now showing its POC chemistry solution at medical meetings throughout the country. It expects to ship its first instruments to customers within 90 days.

The CARESIDE Analyzer™, as the company calls its chemistry instrument, comes with 36 FDA-cleared or exempt tests and parameters. CARESIDE's goal is to eventually offer a total of 55 chemistry and hematology assays.

As the POC chemistry analyzer comes to market, CARESIDE expects to have a POC hematology analyzer ready sometime during first quarter 2000.

"We plan to have three components to the CARESIDE lab system," said W. Vickery Stoughton, Chairman and CEO of CARESIDE. "There will be a chemistry analyzer, a hematology analyzer, and a software solution which will connect both of these instruments to other lab instruments, as well as the various information systems in the lab or healthcare enterprise."

THE DARK REPORT predicts that CARESIDE's POC analyzers will cause a radical change to the existing system of core lab/stat lab systems operated by both hospitals and independent commercial laboratories, for a fundamental rea-

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

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son. CARESIDE's point-of-care analyzers are capable of performing the majority of high-volume, routine tests in a near-patient setting.

It appears that these instruments possess robust design quality and will deliver accurate results in a cost-effective manner. As a point-of-care solution, CARESIDE's analyzers will allow doctors to get results in just 15 minutes, instead of waiting for the typical two to 24-hour turnaround needed in today's clinical laboratory environment.

Decentralize Lab Operations

"From the beginning, our goal at CARESIDE has been to bring high-quality testing closer to the patient, and in the process, decentralize laboratory operations and reduce the cost of laboratory services," explained Stoughton.

To accomplish this, CARESIDE used a classic application of the 80/20 Rule. "Most laboratorians know that a small number of routine, high-volume assays make up the majority of diagnostic tests performed each year in the United States," noted Stoughton. "We identified the top 70 tests, by volume.

"Virtually all of these are routine chemistry and hematology tests," he continued. "We designed our POC analyzers to perform these tests. This now makes it possible to reconfigure the organization of clinical laboratories in both hospital and commercial lab settings and move these tests out of core labs."

Moving Chemistry Tests

The chemistry analyzer that CARESIDE developed is an elegant, simple solution for moving chemistry tests out of the centralized, high-volume laboratory. It is also compact, taking up less than one square foot of tabletop.

From first glance, it closely resembles the original MacIntosh computer of 1984. A plastic exterior case holds the touch screen window and a slot to accept the individual test cartridges.

THE DARK REPORT, in a site visit to CARESIDE's headquarters in Culver City, California, watched the analyzer operate. It can hold up to six cartridges of a single patient's blood at one time. Most cartridges contain one test, but some cartridges are capable of two or three tests. Under refrigeration, cartridges have a shelf life of about 18 months.

Test cartridges are a little smaller than the typical business card, and about 3/8 of an inch thick. The single use cartridge contains the reagent and uses channels to properly prepare the specimen, whether it's serum, plasma, or whole blood. Sample sizes are small, about 75 to 100 microliters of whole blood.

Once the operator has loaded the cartridges and input patient information and test orders, the analyzer automatically launches cycles for heating, centrifuging, and several types of reading. Used cartridges eject from the side into a waste container. The entire process takes about ten to 15 minutes. Other details about this analyzer are listed in the sidebar on the opposite page.

Simple Analyzer To Use

"This is a very simple analyzer to use," stated Thomas H. Grove, Ph.D., Executive Vice President of Research and Development. "It has been designed so that non-technical personnel, after appropriate training in the device, can operate and maintain it."

Despite its ease of use, the CARESIDE Analyzer is actually a highly-sophisticated instrument, capable of meeting the expectations of the most sophisticated laboratorian. Dr. Grove explains. "Not only do we offer a comprehensive test menu, built upon the best testing technology, but we have invested considerable effort in the information management capabilities of the instrument itself.

"For example, we have embedded all the relevant quality assurance/quality

CARESIDE Launching POC Chemistry & Hematology

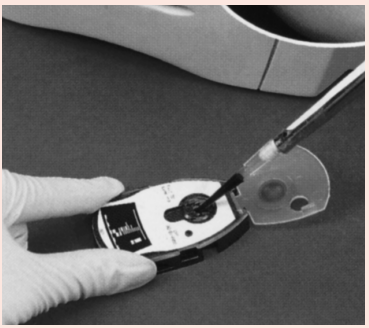
CARESIDE, Inc. *is the first company to design a complete point-of-care system for routine chemistry and hematology. It will make it possible for laboratories to move high-volume, routine testing out of the centralized laboratory and into point-of-care settings, including doctors' offices, hospital wards, nursing facilities, and urgent care centers.*

CARESIDE, Inc.
At-A-Glance

Headquarters:	**Culver City, CA**
Founded:	**1996**
# of FTEs:	**55**
Shares Outstanding:	**5.4 million**
AMEX Symbol:	**CSA**

Chairman of the Board & CEO:
W. Vickery Stoughton

Executive Vice President, Research & Development
Thomas H. Grove, Ph.D.



This shows a test cartridge and one method for charging it with the specimen. The chemistry analyzer can hold up to six cartridges at one time.

Chemistry & Electrochemistry Assays
(Cleared/Exempt for professional lab use)
Glucose
BUN (Urea Nitrogen)
Creatinine
BUN/Creatinine Ratio
Albumin
A/G Ratio (calc)
Globulin
Total Cholesterol
HDL-Cholesterol
LDL-Cholesterol (calc)
Cholesterol/HDL
Cholesterol Ratio
GGT
ALT
Total Bilirubin
Phosphorus
Total Protein
Uric Acid
Triglycerides
LDH
Total Calcium
Alkaline Phosphatase
Osmolality (calc)
Amylase
AST
ALT/AST Ratio
Creatine Kinase
Creatine Kinase MB
Percent CKMB
Ammonia
Magnesium
Chloride
Potassium
Sodium
Carbon Dioxide
Anion Gap

Planned for submission in 1999:
Bilirubin, Direct
Hemoglobin

Coagulation:
(Cleared/Exempt)
PT
(Submitted or Planned)
APTT
Fibrinogen
Thrombin Time

Immunochemistry:
(Planned)
Digoxin
Theophylline
Phenytoin

Hematology:
(Planned)
Red Blood Cells
Hematocrit
Hemoglobin
Platelet count
RDW
MCV
MCH,
MCHC
White Blood Cells
Lymphocyte Count
Percent Lymphocytes
Monocyte Count
Percent Monocyte
Granulocyte Count
Percent Granulocyte
Platelet Count
Mean Platelet Volume

control requirements affecting lab operations, such as CLIA," he said. "It is easy to develop Levey-Jennings charts and set the parameters for testing. We believe our analyzer can meet the needs of even the most demanding laboratorian."

As of press time, CARESIDE's chemistry analyzer has pre-market clearance for professional laboratory use of the CARESIDE Analyzer and 36 blood tests. There is a 510K submission with the FDA to obtain authorization for its use in point-of-care settings and physician office laboratories.

The hematology instrument is expected to be ready for market during the first quarter of 2000. CARESIDE is filing FDA applications sequentially for additional assays in chemistry, coagulation, and immunochemistry.

Marketing Trials

Marketing trials are about to start in a variety of settings. These trials will be undertaken at hospitals, large integrated healthcare systems, nursing homes, physician group practices, and home health care agencies. Marketing trials are intended to go beyond clinical trials data and demonstrate the effectiveness of the instrument system in actual day-to-day clinical use.

"Our planned menu of approved assays is intended to cover 80% of the types of blood tests ordered on an outpatient basis," noted Dr. Grove. "We are now building up a sales force to introduce our products to laboratories throughout the United States."

Cost of the CARESIDE Analzyer will be under $10,000. Individual test cartridges will have a retail list price of between $4.25 and $8.25, depending on the type and number of tests that a particular cartridge can run.

"Once final clearances are in place for our complete POC system," stated Dr. Grove. "we expect it to be used by commercial laboratories, hospitals an integrated delivery systems, physician offices, nursing homes, and similar care environments."

End of Centralized Labs

Expect CARESIDE's POC system to get a lot of attention, once laboratorians have a chance to evaluate it. THE DARK REPORT predicts that this new point-of-care technology, along with future competing products, will effectively mean the end of centralized laboratories doing routine testing.

This will change the structure and organization of hospital laboratories. It will also force independent commercial labs, including the two blood brothers, to radically revamp the way they provide lab testing services to physician offices.

For example, SBCL was preparing to put the CARESIDE system into some of its phlebotomy stations, located in physician office buildings. This would give it the capability to do rapid turnaround on routine testing and give it a competitive advantage over rival laboratories. It is uncertain whether Quest Diagnostics Incorporated, the new owner of SBCL, will pursue this business strategy.

Revolutionary Technology

Laboratory executives and pathologists should understand that this type of point-of-care testing technology is revolutionary. CARESIDE is first to market with its solution, but others will follow. During the next 24 months, this will become a highly competitive field.

The cumulative effect of pushing routine testing closer to the patient will be the end of centralized clinical laboratories as we know them today. It will bring about a change in the structure of both hospital labs and independent commercial laboratories. TDR

Contact W. Vickery Stoughton and Thomas H. Grove, Ph.D. at 310-386-6767 or through careside.com.

"Distributed" Lab Model Soon to Become Reality

POC testing to be more revolutionary than laboratory automation technology

By Robert L. Michel

CEO SUMMARY: During the 1990s, laboratory automation was expected to have the greatest impact upon the structure and organization of laboratories. However, like the famous race between the tortoise and the hare, it's our prediction that point-of-care testing technology, quietly advancing in the background, will have a more revolutionary impact on the way clinical laboratories are organized and operated.

IT'S TIME TO RECOGNIZE and welcome what may be the most transformational technology to hit the clinical lab industry in three decades.

With the arrival of **CARESIDE, Inc.**'s revolutionary point-of-care (POC) technology for routine chemistry and hematology testing, a new force for change has been unleashed within the clinical laboratory industry.

THE DARK REPORT predicts that CARESIDE's arrival in the marketplace will trigger a fight by diagnostics companies to control the market for high-volume, routine testing. CARESIDE's goal is to move the 70 most frequently ordered routine tests out of the centralized core laboratory and into the point-of-care setting.

Moving Routine Testing

CARESIDE will need to demonstrate the viability, performance, and economic justification for its products. Even as that happens, competing diagnostic companies will be rushing to introduce their own solutions for moving routine testing out of centralized labs and into the point-of-care setting.

For that reason, THE DARK REPORT expects that the next 24 months will see the introduction of a variety of innovative POC products and systems. Existing competitors cannot cede the routine testing market to new entrants like CARESIDE.

Economic Rationale

But there will be a far greater impact to the clinical laboratory industry than increased competition for POC testing solutions. The ability to move routine testing outside the centralized laboratory will trigger the next revolution in clinical laboratory practices. POC testing undermines the existing clinical and economic rationale behind centralized laboratory testing.

For that reason, POC technology has the potential to recast the structure and organization of clinical laboratories. Once the economics of doing routine chemistry and hematology testing at the point-of-care are demonstrated and val-

DARK REPORT Predicts Three Revolutionary Changes

IT WILL BE QUITE A MILLENNIUM for the clinical laboratory industry. THE DARK REPORT predicts three revolutionary changes will occur during the next few years.

1. WEB-BASED LAB TEST ORDERING AND REPORTING:

OUR PREDICTION: Within 24 months, virtually every physicians' office in the United States that generates a significant volume of lab tests will be using a web-based system for test ordering and results reporting.

PROBABLE IMPACT OF THIS CHANGE: Commercial laboratories and hospital lab outreach programs will need to offer this service to their physician clients, or lose that account to competitors. Nimble labs can use web-based lab services to capture market share from slower competitors.

2. POC TESTING FOR HIGH-VOLUME, ROUTINE LAB TESTING

OUR PREDICTION: During the next 36 months, CARESIDE and diagnostics competitors will introduce a variety of effective POC instruments that enable high-volume, routine tests to be done outside core laboratories, at lower cost and with equal or better quality.

PROBABLE IMPACT OF THIS CHANGE: As new POC technology demonstrates its cost and quality advantages, both hospital and commercial laboratories will decentralize routine testing. Core labs will continue to perform reference and esoteric testing.

3. LABORATORY AUTOMATION:

OUR PREDICTION: The arrival of POC technology for routine testing means that laboratory automation loses its importance, and its potential, to significantly lower costs in the centralized laboratory.

PROBABLE IMPACT OF THIS CHANGE: total laboratory automation (TLA) and modular/workstation automation will become focused on supporting reference and esoteric testing.

idated, the era of total lab centralization, supported by rapid response lab networks, will be at an end. Emerging will be a new era dominated by what some lab futurists already term the "distributed" laboratory.

Simply put, the distributed laboratory organization is embedded within all segments of the integrated healthcare system. The majority of lab tests do not flow to a central, or core, laboratory. To the contrary, the preponderance of lab testing is done literally at any site where care is provided.

Although "distributed lab" seems to the the more popular term to describe this type of laboratory system, THE DARK REPORT believes that "dispersed" is an equally descriptive term for the next generation of lab organizations.

Whether distributed or dispersed, what this POC technology will do is force laboratorians to leave their centralized laboratory citadels. They will naturally migrate out into the general clinical environment. CARESIDE's W. Vickery Stoughton discusses some of the ways this will occur in his exclusive interview, found on pages 9-13.

Change The Lab Industry

Thus, THE DARK REPORT has two fundamental predictions to make about how POC technology will change the clinical laboratory industry during the next 24 to 48 months.

First, CARESIDE's point-of-care testing system for chemistry and hematology will stimulate a competitive war among diagnostic companies.

By making it economically feasible to move routine testing out of the core laboratory, CARESIDE threatens the revenues and profits of the billion-dollar diagnostics giants.

Roche Diagnostics, **Abbott**, **Ortho-Clinical Diagnostics**, **Beckman-Coulter**, and others will not stand idly by and watch CARESIDE and similar POC competitors steal their routine testing business.

Defend Their Business

It is reasonable to expect that these companies will devote considerable resources to adapt their existing diagnostics technology and develop their own versions of POC instruments. Their goal will be to rush these to market and defend their existing business from CARESIDE and similar POC vendors.

The consequence of this will be self-fulfilling. The variety and range of POC solutions for routine, high-volume testing will improve the economics of decentralization. This will literally force laboratory administrators and pathologists to realize those cost savings by decentralizing their laboratories.

How quickly will this POC product race play out? CARESIDE engineered its solution from scratch in about 36 months, and for an investment of only about $20 million! It would be reasonable to expect that the billion-dollar diagnostic giants, with their existing intellectual property, patents, and access to capital, can cut this time in half.

Changes Within 24 Months

So, just like the web-based lab test ordering/results reporting that we discussed in the last issue of THE DARK REPORT *(see TDR, November 1, 1999)*, we believe that FDA-cleared products to support routine chemistry and hematology testing at the point-of-care will begin appearing within 24 to 36 months.

Which brings us to our second prediction. The economics and availability of reliable POC testing for chemistry and hematology will launch a revolution in the structure and organization of clinical laboratories.

For the first time in the modern era of laboratory medicine, it will actually be better to have the test done outside a centralized laboratory. The total cost per reported result will be lower. The quality will be equal if not better (not the least because the specimen is tested within minutes of collection), the doctors and nurses can have results within minutes of drawing blood, and the QA/QC of the instrument can be monitored remotely by trained laboratorians.

Certainly, this is a revolution in the management, organization, and structure of clinical laboratories. It raises the survival stakes for both hospital and commercial laboratories. Those labs which move decisively to implement valid POC technology for routine testing will have the competitive edge over those labs which do not.

POC Not The Only Force

POC technology will not be the only force driving laboratory decentralization. Web-based lab test ordering/reporting makes it easier to connect remote instruments with the laboratory. And remember "lab on a chip?" Companies like **Affymetrix** continue efforts to miniaturize test technology.

Expect the cumulative effect of these technologies to reinforce one dominant trend: reducing the size of the centralized laboratory by making it possible to do sophisticated, reliable lab tests in near-patient and point-of-care settings.

THE DARK REPORT is aware of other technologies and changes to laboratory management which reinforce these broad themes. Stay tuned for additional intelligence and analysis. **TDR**

Contact Robert Michel, Editor, at 503.699.0616 or labletter@aol.com.

CARESIDE POC Solution To Alter Lab Organization

"To capture...full...savings, it is necessary to substitute, in entirety, the traditional way of performing tests in the centralized laboratory for a decentralized laboratory system."
W. Vickery Stoughton, Chairman, CARESIDE, Inc.

Decentralizing routine, high-volume lab testing now possible with this new POC technology

CEO SUMMARY: CARESIDE's point-of-care testing system gives laboratory executives a new tool for bringing value-added laboratory services to clinicians. In this exclusive interview, W. Vickery Stoughton, Chairman and CEO of CARESIDE, Inc., shares his perspectives on the clinical laboratory marketplace. As President of SmithKline Beecham Clinical Laboratories, Mr. Stoughton was responsible for starting the effort to create a point-of-care solution for routine chemistry and hematology testing. Here are his thoughts and predictions for how POC technology may decentralize routine laboratory services.

EDITOR: It's important for thought leaders in clinical laboratory management to understand why **CARESIDE, Inc.**'s new point-of-care (POC) chemistry and hematology instruments were brought to market. I would also like for you to explain why these instruments, and others like them, will trigger important changes to the structure of both hospital labs and commercial laboratories.

MR. STOUGHTON: Robert, the history of CARESIDE is a good starting point. It makes it easier to understand how and why CARESIDE's technology gives laboratory administrators and pathologists a new tool to lower laboratory costs and provide physicians with improved lab services.

EDITOR: CARESIDE was originally part of **SmithKline Beecham Clinical Laboratories** (SBCL). Why did SBCL decide to get into point-of-care lab testing?

MR. STOUGHTON: In 1993, a group of us at SBCL decided to look at several emerging technologies which had the potential to alter the economics of laboratory testing and change the role of commercial laboratories within the healthcare system.

EDITOR: Was this a strategic study exercise to identify transformational technologies and develop a business plan to minimize their potential negative effects to SBCL's core business?

MR. STOUGHTON: Yes. We identified three technology areas which might alter the economics of laboratory testing. They were laboratory automation, point-of-care testing, and information management capabilities.

EDITOR: That's interesting. Since 1993, laboratory automation has yet to make a huge dent in the clinical lab world. POC is certainly *not* a dominant influence today, and enhanced information management technology is only now on the verge of making a widespread impact. Why did you end up focusing on point-of-care testing as a strategic response?

MR. STOUGHTON: We did a study of the volume and composition of the lab tests then being done at SBCL. What we learned will not surprise most lab executives. There were 70 individual test assays which generated 60% of the specimen volume coming into the SBCL national lab system annually.

EDITOR: What about the dollar volume from these 70 assays?

MR. STOUGHTON: In 1993, SBCL was generating $1 billion in revenues. These 70 assays accounted for about $350 million in annual net revenue.

EDITOR: What you describe is the classic application of the 80/20 Rule. As you and your team studied these numbers, what concerned you about this situation?

MR. STOUGHTON: Not surprisingly, these 70 assays were high-volume, routine types of tests, centered around chemistry and hematology. We realized that if a diagnostics company were to develop a truly effective point-of-care solution, then SBCL was at risk of losing 60% of its specimen volume and 35% of its annual net revenues.

EDITOR: After this realization, how did you leap from a strategic technology assessment exercise to actually funding a major research and development project for POC chemistry and hematology?

MR. STOUGHTON: In a true sense, we realized SBCL's vulnerability to POC technology, if and when it made it to market. We also recognized that Medicare and the healthcare system were changing. Remember, this is 1993. Managed care is growing rapidly. HCFA and the OIG are making an issue of Medicare fraud and abuse. Fee-for-service reimbursement for lab testing was declining. Capitated and lab risk agreements were increasing. It became obvious to us that we needed to think differently about how to organize and deliver laboratory services.

EDITOR: But why an "invent it yourself" decision for point-of-care testing?

MR. STOUGHTON: We surveyed the diagnostic companies and decided none of the established firms was prepared to cannabilize profits from their existing product lines to sell a POC solution. In 1993, there was little market for such technology. And certainly few reference labs and commercial labs would be willing to extensively reengineer their operations to decentralize routine testing while maintaining centralized testing for esoterics.

EDITOR: Is that why SBCL decided to develop their own POC solution?

MR. STOUGHTON: Our thinking was "we'd better do this ourselves, before someone does it to us."

EDITOR: Initial funding for this POC project was provided by SBCL. When and why did that change?

MR. STOUGHTON: Well, the original project was launched with SBCL in 1994. For various reasons, this project was spun off as an independent company in November 1996.

EDITOR: That company was called **Exigent Diagnostics, Inc.**, which later became CARESIDE, Inc., correct?

MR. STOUGHTON: Yes. We purchased the intellectual property, equipment and other assets from **SmithKline Beecham, PLC** (SB) and SBCL. SB made an investment in our company and we entered into a distribution and supply agreement with SBCL. The SBCL agreements are now held by **Quest Diagnostics, Incorporated** as a result of its acquisition of SBCL.

EDITOR: Incorporated in November 1996, CARESIDE has operated as a separate company. It issued an IPO (initial public offering) in June 1999, raising a net of $12.4 million. Any comments on your relationship with Quest Diagnostics since it acquired SBCL?

MR. STOUGHTON: Not at this time.

EDITOR: Vic, CARESIDE's offering prospectus made this statement: "CARESIDE has developed and plans to sell a proprietary blood testing system called the CARESIDE system. It is *designed to decentralize* laboratory operations." (editor's italics.) THE DARK REPORT believes it is imperative that forward-looking lab executives and pathologists understand what this means to the laboratory organization they operate today. Could we talk *candidly* about why CARESIDE's POC chemistry and hematology instruments have the potential to transform the organizational structure of both hospital labs and commercial labs?

MR. STOUGHTON: Certainly. First, your readers should remember this important fact: CARESIDE exists today because our executive team at SBCL realized that technology and economics were going to change the way clinical laboratories provide testing services, whether we liked it or not.

EDITOR: That is a good point. You acknowledged the future would be different, and you began to rationally prepare for that future. Clients of THE DARK REPORT should keep that in mind as they learn about the changed economics that POC chemistry and hematology will bring to the clinical lab industry.

MR. STOUGHTON: Let me explain the main economic opportunity that our CARESIDE testing solution makes feasible. If you look at the cost of getting a test result in a laboratory, approximately 60% of that cost is devoted to the preanalytical stage and QA/QC. This 60% number includes any courier and distribution costs, accessioning, aliquotting, specimen preparation, as well as QA/QC expenses.

EDITOR: Which means the remaining 40% of test costs involve performing the test itself and reporting the results.

MR. STOUGHTON: That's correct. The economic proposition of our CARESIDE solution is simple. If you take those routine, high-volume tests and move them out of the centralized, core laboratory into our point-of-care system, you can eliminate as much as 90% of those preanalytical and QA/QC costs.

EDITOR: But, although 90% of preanalytical costs incurred by sending the specimen to a core lab can be eliminated, does the CARESIDE POC system add back costs? What are the net savings?

MR. STOUGHTON: Where we get more expensive, obviously, is how we present the test analyte. We don't have the volume-driven, high-throughput economies of scale of today's centralized laboratories. So, on every test dollar we may add back about 20¢. Net these cost components out, and our POC system can generate cost savings of about 35% over the same tests done in a centralized laboratory.

EDITOR: I assume that savings of this magnitude require a total commitment to moving routine assays out of the core laboratory and into the POC setting.

MR. STOUGHTON: To capture that full 35% savings, it is necessary to substitute, in entirety, the traditional way of performing tests in the centralized laboratory for a decentralized laboratory system.

EDITOR: In other words, this new model of laboratory services comes close to that emerging term, "distributed laboratory." This describes a laboratory organized around doing testing where it makes the most sense, whether patient self-test, home care, point-of-care, rapid response lab, or core lab.

MR. STOUGHTON: Yes. In the hospital, for example, our CARESIDE instru-

ments would be placed where the nurses generate the specimens and get results within minutes. This permits the hospital to remove the hematology, chemistry, coagulation, and other instruments from the core lab. These tests migrate nearer to the patient. The core lab is then organized around reference and esoteric testing. Thus, the CARESIDE instrument is not a cost add-on to the system, it is a cost replacement. We expect to demonstrate considerable cost savings from this decentralized testing model.

EDITOR: You mentioned nurses as involved in the POC testing. Their participation in lab testing and phlebotomy is certainly a regular point of dispute in many hospital settings.

MR. STOUGHTON: True, but there are several models for labor that you can use. For example, the phlebotomist could perform the test at the time of the draw. In some situations, I would expect that time and motion studies on nursing would document that nurses spend a significant amount of time chasing results and getting them to doctors. However, if these same nurses were to do the POC testing and gain immediate access to the results, there would probably be a net productivity gain, and the nursing staff would be happier.

EDITOR: What about the concept of a laboratory test cart?

MR. STOUGHTON: That is certainly another model. In fact, pharmacies used to be centralized in the basement of the hospital, then "unit dose" carts came along, and now the clinical pharmacist comes into the nursing units to work directly with the care team. The CARESIDE system can now allow laboratorians to take a med tech, and in a similar way as the clinical pharmacist, have the med tech directly involved with the care team, providing lab test results and interpretation directly to the clinicians and nursing staff. Med techs would find it a much more stimulating work environment than today's situation, where they are relegated to the centralized laboratory and any communications with the care team are generally by telephone.

EDITOR: Vic, your point-of-care lab testing models are consistent with our message here at THE DARK REPORT. We firmly believe that the future of clinical laboratory medicine lies, not in simply generating test results, but in helping clinicians use those test results to improve healthcare outcomes while lowering the cost of care. Thus, laboratorians will be using their minds and their knowledge to support clinical decisions. You are on target in suggesting that med techs can move to the point-of-care along with routine chemistry and hematology testing. This puts them right in the midst of the action, and increases their ability to positively influence clinical practices.

MR. STOUGHTON: That could come to pass.

EDITOR: Another topic I would like you to share with clients of THE DARK REPORT is the fundamental shift in the structure and form of clinical laboratories that is about to occur. It's this concept of decentralizing routine testing by moving it to the POC setting.

MR. STOUGHTON: Decentralization is a key theme in the business world today. Most all the technology enhancements to diagnostic testing now moving through the development pipeline will encourage and support decentralized-laboratory testing.

EDITOR: You believe that laboratory decentralization will follow the same path as other industries, is that not true?

MR. STOUGHTON: Basically, yes. I would ask your readers to compare what is soon to happen within the clinical laboratory industry to the business situation of **IBM Corporation** in the early 1980s.

EDITOR: Please explain.

MR. STOUGHTON: IBM provided business with a complete line of large, centralized computers. It was the largest, most profitable, and most admired company in the computer industry. But IBM was incapable of understanding the impact that personal computers would have in the way corporations managed information.

EDITOR: Would you explain that, please.

MR. STOUGHTON: Both IBM and its customers were committed to centralized information system technology. IBM made billions of dollars in selling this equipment. But IBM was not willing to adapt and pursue the business opportunities presented by the personal computer as it arrived on the scene.

EDITOR: But IBM's first PC was the machine that set the standard for personal computers.

MR. STOUGHTON: That shows you the influence that IBM had, and how it went unfulfilled. IBM had such clout and respect in the marketplace that any technology solution it offered business was immediately accepted. IBM's PC solution became the PC industry standard, but IBM would never devote its resources into developing a cost-competitive PC product. **Compaq Computers** built an IBM-PC clone, undersold IBM, and became a billion-dollar company in less than 24 months. Its computer solution for business was decentralized information processing.

EDITOR: Meaning that it moved information management out of the centralized data processing center and out to desktops, to where people actually did the work.

MR. STOUGHTON: Yes, and then just a few years later, **Dell Computers** came along, and stole Compaq's market from it, with a just-in-time manufacturing strategy that allowed it to undersell Compaq and IBM. Dell figured out a way to be even closer and faster to the customer than Compaq.

EDITOR: There seems to be two lessons in your story. First, when information decentralized, IBM lost its market dominance because it refused to change, making Compaq the winner. Second, just-in-time manufacturing is similar to point-of-care testing. Dell Computer moved closer to the customer with its manufacturing, and knocked Compaq off the mountain.

MR. STOUGHTON: Those are good lessons. My point in telling the IBM story is that the clinical laboratory industry must realize that customers will drive the shift from centralized laboratories to decentralized laboratory testing. It's going to happen, and all the supporting elements already exist in the healthcare marketplace.

EDITOR: If I listen carefully to what you are saying, your message is basically that physicians and caregivers are ready to embrace laboratory testing solutions which give them faster and accurate results while controlling or reducing the cost of lab testing.

MR. STOUGHTON: That's correct. Laboratories must be willing to respond to their customer's expectations for faster turnaround times and more convenient, accurate testing capabilities. One way to accomplish this is by moving routine testing out of the centralized, core laboratory and closer to the customer.

EDITOR: It is certainly true that knowledgeable experts confidently predict an explosion in patient self-testing, home care testing, near patient testing, and point-of-care testing. The core lab will continue, but it will be dedicated to doing reference and esoteric work. This is lower volume, higher proficiency types of testing.

MR. STOUGHTON: That is why it is important for laboratorians to understand that all these new technologies, including the CARESIDE system for routine chemistry and hematology, contribute to

improving the overall value of laboratory testing to the healthcare community.

EDITOR: Before we end this interview, I would like you to address the concept of decentralizing routine testing in greater detail. This runs against the training and experience of so many hospital laboratory directors and clinical pathologists.

MR. STOUGHTON: Robert, that is partially true. But I think the real challenge will be to get hospital administrators to think in other terms besides the core laboratory. Most laboratory directors are quick to incorporate improved lab testing technology, once they see it validated in actual clinical practice.

EDITOR: I'd agree with that.

MR. STOUGHTON: Hospital administrators, on the other hand, are not so close to laboratory technology. Thus, getting them to accept the fact that they don't need a central laboratory for routine testing will be a big challenge. I can speak from first-hand experience on this point. During my career, I was responsible for integrating the laboratory functions for two large hospitals, involving 1,700 beds.

EDITOR: As your POC system enters the marketplace, there will be reluctance by senior hospital administration to abandon the centralized laboratory model. On one hand, this business model has proven reliable. On the other hand, few hospital administrators are willing to risk problems by being the first to eliminate the centralized lab in favor of doing routine chemistry and hematology at the point-of-care.

MR. STOUGHTON: We are optimistic that acceptance of the CARESIDE system will happen relatively quickly.

EDITOR: Why is that?

MR. STOUGHTON: First and foremost, we anticipate that laboratories will find the economics to be compelling. Here is a new model for doing routine, high-volume testing that can save up to 35%, when adopted in entirety, over doing the same tests in a centralized laboratory.

EDITOR: What about other benefits and incentives?

MR. STOUGHTON: There are several, and most are obvious to laboratorians. Get doctors used to a 15-minute turnaround time on tests and they will become ardent supporters. Then there's the improvement in specimen quality. POC means fewer problems with specimen mishandling and specimen deterioration. And, the sooner the test is run after the draw, the better the test result.

EDITOR: Do you think there will be resistance by payers and inadequate reimbursement?

MR. STOUGHTON: No. The CARESIDE system provides cost-competitive test results. By its design, it makes it easier to meet and document medical necessity. We believe that payers will recognize these features and reimburse for this technology.

EDITOR: In closing, Vic, is there anything else you would like to add?

MR. STOUGHTON: I would encourage those laboratorians who embrace the idea of value-added laboratory testing services to contact us directly for more information. We are very much interested in working with progressive laboratory organizations that are ready to pursue the benefits of decentralizing routine lab testing.

EDITOR: Thank you very much for some powerful insights into the laboratory marketplace.

MR. STOUGHTON: You're welcome. We appreciate the opportunity to share some significant points about the future direction of the clinical laboratory industry. TDR

Contact W. Vickery Stoughton at 310-386-6767 or through careside.com.

The Dark Index

Abbott Runs Into FDA Buzzsaw, Faces Major Marketplace Crisis

Second largest diagnostics manufacturer forced to pull a multitude of lab test products

BY NOW, MOST OF THE clinical laboratory industry knows that **Abbott Laboratories, Inc.** signed a consent decree with the **Food and Drug Administration** (FDA) on November 2, 1999.

Under terms of the consent decree, Abbott paid a $100 million fine and will pull a number of test kits out of the marketplace. The original date for this action was to be December 6, 1999. But today in a U.S. District Court, the consent decree was amended, allowing Abbott to sell the affected products through January 10, 2000. This is to give clinical laboratories and blood banks additional time to adjust to the situation.

The impact of this consent decree will be significant. Abbott is taking a $168 million charge this quarter to cover the fine paid to the government and write down the value of the affected inventory. In addition. Abbott disclosed to analysts that it expects to lose about $250 million in revenue during 2000 as a result of the FDA's action.

Test Kits and Reagents

Within the laboratory industry, there has been much discussion about the meaning of the FDA's action against Abbott and how it relates to the quality of Abbott's test kits and reagents. Abbott's influence is considerable, since it markets 325 different tests.

At issue is Abbott's adherence to the FDA's Good Manufacturing Practice and Quality System for a six-year period starting in 1993. The FDA claims that, despite repeated inspections and warnings, Abbott failed to comply with these manufacturing requirements.

Widespread Resistance

Concern about manufacturing practices and quality is justified. The FDA's requirements are consistent with ISO-9000 manufacturing guidelines. These spell out a work process which is designed to build products correctly, by design, thus eliminating the need to inspect the output to identify defects.

This is where the term three sigma and six sigma originates. This is a manufacturing process that, when "in control," produces less than six defective parts per thousand or per million, respectively. Obviously, if the process is "out of control," identifying a small number of defective parts becomes difficult, if not impossible.

In the case of Abbott, breakdowns in monitoring and documenting the manufacturing process gave the FDA reason to question whether Abbott's manufacturing processes were consistently "in control," thus insuring that the finished products meet specifications.

The FDA's consent decree was to insure that Abbott's manufacturing processes were unquestionably producing a consistent and high-quality product. Since, by design, finished output is not inspected, this is a prudent step. TDR

Lab Industry Briefs

MCKESSON HBOC ACQUIRES ABATON.COM IN MOVE TO WEB SERVICES

IT WAS VALIDATION OF A PREDICTION made just weeks ago in THE DARK REPORT that web-based information management systems is the next major battleground in both healthcare and the clinical lab industry.

McKesson HBOC announced its purchase of **Abaton.com, Inc.** of Minneapolis, Minnesota last Tuesday. Abaton.com offers products for managing clinical data, particularly lab test results and prescriptions. Abaton.com is an early entrant in the race to move lab test ordering/results reporting onto the Internet. *(See TDR, November 1, 1999.)*

McKesson HBOC also announced a three-year deal with **Claimsnet.com, Inc.** of Dallas. This company has products to allow small physician groups to transmit insurance claims to payers via the Internet.

These agreements show that major healthcare IS vendors are making serious moves to add Internet tools to their existing proprietary software products. McKesson HBOC did not disclose when its Internet products and solutions would be ready to market.

QUEST DIAGNOSTICS ANNOUNCES FIRST ROUND OF LAB CONSOLIDATIONS

AS EXPECTED, **Quest Diagnostics Incorporated** is moving swiftly to rationalize laboratory operations after its acquisition of **SmithKline Beecham Clinical Laboratories** (SBCL) in August.

Last week, the company announced seven specific laboratory sites where a laboratory would either close or undergo a major downsizing. It expects that 18 months will be required to implement these changes.

Without giving a specific number, Quest acknowledged that these changes would reduce employment by between 1,250 and 2,500 people.

On the West Coast, all the reference and esoteric testing now done at the former SBCL laboratory in Van Nuys, California will be moved to Quest Diagnostic's Nichols Institute facility in San Juan Capistrano.

As a result of this consolidation activity, Quest Diagnostics estimates it will take a pre-tax charge of $160 million during the fourth quarter, meaning that it will report a loss for this financial period.

UNILAB SHAREHOLDERS TO VOTE ON PLAN TO TAKE COMPANY PRIVATE

NOVEMBER 23, 1999 IS THE DAY that **Unilab, Inc.** shareholders will vote on whether to approve the proposal to sell the company to **Kelso & Company**.

Kelso is a respected LBO (leverage buy-out) company. It is prepared to pay approximately $420 to acquire substantially all the shares of Unilab. Kelso's goal is to take the company private, boost revenue and income, and look for an opportunity to sell the laboratory at some future date. *(See TDR, June 7, 1999.)*

Earlier this month, Unilab released its third quarter financial report. Revenue jumped 43.3%, from $53.2 million in third quarter 1998 to $76.2 million this year. Net income growth for third quarter was substantial, moving from $3.1 million in 1998 to $17.9 million in 1999.

Much of the growth in revenues and net income is attributable to acquisitions made during the past 12 months. Unilab purchased **Meris Laboratories** and **Bio-Cypher Laboratories** in separate transactions. These two acquisitions added about $80 million in revenue to Unilab.

However, increased pricing also played a part in Unilab's growth. The lab realized a price increase of approximately 8.7% for the quarter over third quarter 1999. That is a significant accomplishment, given California's tough managed care marketplace.

LABONE MOVING TO BUILD NATIONAL SERVICES

IT'S AN EXPANSION in the national marketplace. **Lab*One*, Inc.** of Lenaxa, Kansas will acquire **World Wide Health Services, Inc.** of Voorhees, New Jersey.

World Wide provides examination and information services to life and health insurers throughout the United States. It has annual revenues of $9 million. Lab*One* is a major provider of medical tests and other services to life insurers. Lab*One* intends to operate its acquisition as a wholly-owned subsidiary, to be called ExamOne World Wide.

LabOne continues to build a diversified business built around laboratory testing. Along with its life insurance testing, it offers clinical testing in the Kansas City area, national drugs of abuse testing, and a laboratory test benefit program called LabCard. *(See TDR, April 29, 1996.)*

EPITOPE PREPARES SALIVA-BASED DRUGS-OF-ABUSE TEST

HERE'S ANOTHER EXAMPLE of a technology change in diagnostic testing. **Epitope, Inc.** of Beaverton, Oregon is working to adopt its OraSure saliva testing technology to drugs-of-abuse testing. The company expects to have the product ready to market early next year.

Epitope believes an OraSure drugs-of-abuse test will be readily accepted in the $350 million per year market for such testing. It offers ease of use, eliminates the chain-of-custody issues associated with urine testing, and allows for a confirmatory test to be performed on the original OraSure sample.

STC Technologies and Lab*One* will partner with Epitope in this effort. Lab*One* pioneered using the OraSure test for HIV in its life insurance testing business. Lab*One* and Epitope have a close business relationship. Epitope is boosting its sales force in preparation for the product launch into the drugs-of-abuse marketplace.

DISEASE MANAGEMENT IS GOAL OF NEW ASSOCIATION

EARLY THIS SUMMER, A NEW GROUP was formed. Called the **Disease Management Association of America** (DMAA), it hopes to advance the practice of disease management.

Based in Wellesley Hills, Massachusetts, the new association hopes to accomplish this through standardizing definitions, program components, and outcomes measures.

Given the importance of laboratory testing for diagnosis, prognosis, and patient monitoring, it would seem that the DMAA would be a perfect place for clinical laboratories to make a contribution in developing disease management protocols, but THE DARK REPORT is unaware of any involvement by laboratories or laboratory trade associations.

Participating on DMAA's board are **Accordant Health Services**, **Blue Cross Blue Shield Association**, **Humana, Inc.**, **Pfizer Health Solutions**, and **SmithKline Beecham Healthcare Solutions**. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

UroCor, Inc. of Oklahoma City, Oklahoma is losing its long-time Chairman and CEO. Effective December 31, 1999, William A. Hagstrom will leave the company to pursue "new business start-up activities." Hagstrom joined UroCor back in 1989, and helped it emerge from a Chapter 11 bankruptcy reorganization. For four consecutive years in the early 1990s, UroCor made *INC. Magazine's* Fastest-Growing business list. UroCor offers diagnostic and therapeutic services to urologists throughout the United States. It is an innovative firm which is a pioneer in attempting to provide physicians with both diagnostic services and therapeutic products.

ADD TO: UROCOR

UroCor's new President and CEO will be Michael W. George, who joined the company in August 1998. George was formerly with **DuPont Merck Pharmaceuticals**, where he was President–International and President–North America.

AMA HITS THE WEB WITH FOR-PROFIT VENTURE

Even the **American Medical Association** (AMA) is now ready to profit from web-based services. It also wants to restore "physician authority" by creating its own Internet service. On October 28, the AMA and six physician associations announced the creation of **Medem Inc.** This company will offer web sites and services to compete with the likes of **drkoop.com**; **Medscape, Inc.**; and **Web/MD**. "We are trying to put the physician back in to this information loop," commented Joe Sanders, Jr., M.D., who is Executive Director of the **American Academy of Pediatrics**, a participant in Medem.

ADD TO: AMA WEB SERVICE

Critics note that the AMA is exposing itself to potential conflicts of interest by supporting a for-profit Internet company. It was just two years ago when the AMA was forced to back out of an agreement to endorse **Sunbeam Corporation** products in return for a fee.

Dynacare, Inc. continues to build its presence in the South. It recently acquired **Laboratories for Genetic Services**, located in Houston, Texas. Medical Director C. Thomas Caskey, M.D. will stay on. Dynacare will operate this new lab as part of its joint venture with **Memorial Hermann Healthcare System**. The new lab provides genetic testing and counseling services for the areas of prenatal, postnatal, cancer, and FISH testing.

Pathology Consultants of America (PCA) added a new pathology practice to its corporate roster. **Columbus Pathology Associates** of Columbus, Mississippi was acquired by PCA. Since 1997, PCA has provided management services under contract to the Columbus group. The deal includes an independent laboratory. The three Columbus pathologists become part of PCA using an employment model agreement. This is the first such arrangement for PCA. PCA now operates seven outpatient laboratories and has 80 affiliated pathologists.

That's all the insider intelligence for this report.
Look for the next briefing on Monday, December 13, 1999

MARK YOUR CALENDARS!

EXECUTIVE
WAR COLLEGE DATES

MAY 16-17, 2000

Fairmont Hotel, New Orleans

(Laboratory CEO Day—May 18, 2000)

UPCOMING...

- ***THE DARK REPORT'S Annual "State of the Laboratory Industry" Review.***
- ***Nano-Sized Semiconductor Technology Promises Low-Cost Multiplex Test Capability.***
- ***Pathology Management Companies Find New Business Niches Amidst Collapse of PPM Industry***
- ***Hospital Lab Outreach Programs Hit Home Runs with Local Physicians.***