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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

Many Laboratorians Seem to Be "From Missouri"

OUR STORY ABOUT THE NEW, STATE-OF-THE-ART AUTOMATED LABORATORY at **Kaiser Permanente Northwest** (KP-NW) in Portland, Oregon is one which should not be overlooked or underestimated in its importance.

It is the story about how an ISO-9000-certified clinical lab organization used ISO principles to design, from the ground up, its new laboratory. Around the offices of THE DARK REPORT, we believe it's the first example of an ISO-certified laboratory building a new clinical lab facility in the United States. By using these long-proven principles of quality management, KP Northwest's lab division created a paradigm-shifting design for laboratory work flow—one that meets all the goals of modern laboratory management.

These goals include improving productivity, reducing both variability and errors in work processes, cutting costs, improving turnaround times and the quality of lab test results, supporting patient safety goals, and providing laboratory staff with a positive work environment that uses their professional skills to best advantage. That's a pretty impressive list of goals well-met. The unorthodox design and operation of this lab is a direct result of clinical lab professionals mastering the tools of quality management (through their ISO-9000 certification), then applying them to the operational problems common to almost all clinical laboratories.

Yet, these quality tools have been around for almost two decades. So why did it take the laboratory profession so long to produce its first clinical laboratory facility designed from the perspective and philosophy of ISO-9000? Maybe our editor-in-chief is right when he compares the typical laboratorian to those famed folks from Missouri. Dubbed the "Show Me" State, Missourians were the type of people who had to be shown something before they would believe it. "I'm from Missouri. Show me!" described the skepticism, often unwarranted, which marked someone native to that state.

Lab managers and pathologists have a cautious nature about new management ideas, particularly when they originate outside the lab industry and healthcare in general. That is why, two decades down the road, few lab managers are familiar with the principles of quality management and even fewer use them extensively in their own lab. However, the KP Northwest lab facility now provides the kind of "show me" evidence that should encourage other lab leaders to learn and deploy the tools of quality management. TDR

Are Two Blood Brothers Using Economic Clout?

Impact from acquiring four large competitors in 2003 shows up in second quarter earnings

CEO SUMMARY: Quest Diagnostics Incorporated and Laboratory Corporation of America now dominate the national marketplace for testing referred by physicians' offices. Release of their second quarter earnings reports provides the first look at their performance following the acquisitions in 2002 which removed American Medical Laboratories, Dynacare, DIANON Systems, and Unilab from the marketplace .

WITH THE RELEASE OF SECOND QUARTER earnings by **Quest Diagnostics Incorporated** and **Laboratory Corporation of America**, the lab industry has its first opportunity to gauge the impact of last year's four big lab acquisitions.

That acquisition wave created a significant restructuring of the competitive market for testing that originates in physicians' offices. It removed **American Medical Laboratories**, **Dynacare**, **Unilab**, and **DIANON Systems** as competitors to the two blood brothers.

It also expanded the geographical reach of the two blood brothers, giving them additional cities where regional laboratories were operated by the lab firms they acquired. One important consequence of these acquisitions is that the market for lab testing services delivered to office-based physicians now has two unique, and strategically relevant characteristics. First, it is a national oligopoly. Second, in specific cities where either of the two blood brothers holds a dominant market share, there exists a regional monopoly.

Last year THE DARK REPORT laid out the reasons why this oligopoly and monopoly market situation exists, and why it affects the strategic planning of hospital lab outreach programs that must compete against Quest Diagnostics and LabCorp. *(See TDR, May 13, 2003.)*

Classic economic theory recognizes that markets dominated by oligopolies and monopolies have unique competitive attributes. Among

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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 $11.90 per week in the US, $12.50 per week in Canada, $13.55 per week elsewhere (billed semi-annually).

other things, the economic power, dominant market share, and economies of scale allow oligopolistic and monopolistic companies to squeeze competitors in a variety of ways. Antitrust laws were developed in response to these patterns of behavior, seen in a variety of industries over many years.

...each wants to change the test mix in favor of "esoteric" and "genetic" testing, because of the higher reimbursement attached to those classes of lab tests.

Against this historical background, the emergence of Quest Diagnostics and LabCorp as overwhelmingly dominant companies needs to be recognized in the strategic planning of competing laboratories. Both Quest Diagnostics and LabCorp must generate increased specimen volume and higher earnings to meet the expectations of the investment community.

In that search for additional specimens and revenues, the two blood brothers want to expand their market share in other segments of the diagnostic testing marketplace. There are three obvious targets: 1) hospital testing; 2) anatomic pathology: and, 3) esoteric and genetic testing. Within the hospital testing segment, each company would like to capture inpatient specimens through contract management of hospital labs and/or as a reference testing resource.

Looking At The Numbers

Using this background as a starting point, the second quarter earnings announcements by Quest Diagnostics and LabCorp are noteworthy. Second quarter represents the first few months since they completed their acquisitions and began integrating the operations of their acquired prizes.

First, a look at LabCorp. The impact of the Dynacare and DIANON acquisitions is evident. LabCorp's revenues increased 21.5% for the quarter, to $743.7 million. Specimen volume increased 16% and price per acquisition went up 5.5%, compared to second quarter 2002.

At Quest Diagnostics, revenues increased 14.1%, to $1.22 billion. Specimen volume, measured by requisitions, increased 10% while revenue per requisition increased 3.5%, compared to second quarter 2002. The Unilab acquisition, which closed on February 28, 2003, contributes to Quest Diagnostics' second quarter numbers.

Days sales outstanding (DSO) is comparable, at 47 and 54, respectively, for Quest Diagnostics and LabCorp. However, LabCorp's bad debt expense, at 7.5%, is almost 50% greater than the 4.8% reported by Quest. Reduction of bad debt expense and DSO is a primary goal at Quest Diagnostics. It states that almost 10% of its employees are involved in billing and collections.

Similar Business Goals

From a strategic perspective, both laboratories are effectively pursuing the same objectives to boost financial performance. Each wants to increase specimen volume through acquisitions and its sales force. Each wants to improve pricing. And each wants to change the test mix in favor of "esoteric" and "genetic" testing, because of the higher reimbursement attached to those classes of lab tests.

Because esoteric and genetic testing is a hot button among Wall Street analysts and the investment community, progress in those areas is constantly emphasized by executives at both the two blood brothers. LabCorp, which advertises itself as "the first

Quest and LabCorp — Side-by-Side

For Q2-2003	Quest Diagnostics®	LabCorp Laboratory Corporation of America
Revenue	$1.22 billion	$743 million
▸Rev % increase	14%	21.5%
Net income	$120.4 million	$86.4 million
EBITDA	$258.5 million	$187.4 million
▸EBITDA % increase	32.9%	19.8%
Days sales outstanding	47	54
Bad debt to revenue	4.8%	7.5%

A side-by-side comparison of the financial performance of Quest Diagnostics and LabCorp for second quarter 2003 shows that there are more similarities than differences. Probably the most notable difference is that Quest Dlagnostics has a revenue base that is almost 50% greater than LabCorp.

Source: Public filings by Quest Diagnostics and LabCorp.

national laboratory to fully embrace genomic testing," releases detailed information about the mix of tests and the revenue they generate.

For the six months ending June 30, 2003, LabCorp disclosed that it generated $437.4 million in revenues from genetic and esoteric testing. This was a 13.4% increase over the same period in 2002. By comparison, what LabCorp defines as "core" testing grew 16.2% during the same time.

A more interesting fact is the revenue attached to each category of tests. LabCorp reports that revenue per accession for genomic/esoteric testing was $53.90 and $62.85 for the first six months of 2002 and 2003, respectively. Revenue per accession for core testing was $27.47 and $27.85 for that same time period.

Thus, revenue per accession for genomic/esoteric testing climbed 16.6% over the year, while revenue per accession for core testing only increased 1.4% during that same time. This demonstrates that the clinical value of genomic and esoteric testing encourages higher reimbursement from payers.

Quest Diagnostic states that gene-based testing grew 20% over the previous year, while esoteric testing grew at a rate of 10%. Because of a 10% decline in drugs of abuse testing volumes due to the weak economy, Quest stated its core test volume was essentially flat during the past year.

Blood Draw Trend

Another trend may be indicated by developments within Quest Diagnostics. The company indicates that about 30% of its specimens are drawn by its 1,700 patient services centers (PSC), and this percentage is increasing. This could be confirmation that many physicians are deciding that they no longer want to draw patients in their offices. Instead, they refer their patients to the lab's PSC.

If true, this is a consequence of inadequate reimbursement for blood draws, changes in compliance regulations which affect supplies a lab provides to physician-clients, and even concerns about malpractice liability from in-office blood draws.

Such a trend probably has a negative impact on local laboratories. That's because they must pick up the cost of phlebotomy on those specimens which were, at one time, handled by the physician's office staff.

Liquid Prep Conversion

Another trend of interest is the conversion, by physicians, from conventional Pap smear tests to liquid preparation Pap tests. Quest states that currently 82% of its clients have converted to the liquid-prep Pap test. It doesn't expect the percentage to increase much in future months.

At LabCorp, the conversion rate is 74%. LabCorp believes the upper end will be about 85%, which is in the same range as the predictions at Quest. LabCorp also says that about 50% of its liquid-prep Pap specimens come with a request to reflex with HPV testing if clinically indicated. LabCorp notes that this is one reason why revenues from HPV testing jumped 70% during the past 12 months.

Prospects For Passage

Proposed legislation to impose a 20% co-payment on Medicare Part B laboratory tests was discussed by executives at both companies during their second quarter earnings call. Neither company believes that the final bill which emerges from the Senate-House conference committee will include the 20% co-payment provision. However, both companies hedged that statement, acknowledging that there are many uncertainties in the political process.

Second quarter earnings reports represent only four months since the last of the four major lab acquisitions was completed (Quest closed the Unilab deal on February 28). However, in that short time, some of the strategies and objectives of the two blood brothers have become known.

During the next 12 months, the two blood brothers will launch intense marketing campaigns to promote their particular colorectal cancer screening test.

Both companies will continue to look for growth by acquisition. But THE DARK REPORT believes that the most visible effort will come from efforts by the two blood brothers to acquire new diagnostic technology which is then offered to physicians on an exclusive basis. Such technology can be purchased outright, licensed, or acquired through marketing and distribution agreements.

In fact, THE DARK REPORT will now make one of its famous predictions. During the next 12 months, the two blood brothers will launch intense marketing campaigns to promote their particular colorectal cancer screening test. As this unfolds, it will allow the lab industry to learn whether the exclusive distribution rights to a new test technology can generate worthwhile revenue growth and profits.

As billion-dollar behemoths, both LabCorp and Quest have the economic resources to further expand their market dominance. But size does have its disadvantages. Regional labs, nimble and close to the customer, still hold their own in many cities. That's because local services of the national labs often fall short of physician expectations. TDR

"State of Industry" Report On Molecular Diagnostics

Firm releases its first national survey of labs now performing molecular testing

CEO SUMMARY: Enterprise Analysis Corporation has launched an ambitious survey that will include 150 laboratories performing molecular testing in the United States. Last week it released information about the first 51 labs contacted in this effort. The survey provides an intriguing look at what molecular tests laboratories are performing in the areas of infectious diseases, genetic diseases, coagulation/hematologic, and cancer.

MOLECULAR DIAGNOSTICS is still in its infancy. There is much speculation about the experience of early-adopter laboratories now performing such testing because few studies on this subject have been conducted.

To bring clarity to this situation, **Enterprise Analysis Corporation** (EAC), a healthcare consulting company based in Stamford, Connecticut, has initiated a comprehensive national survey. The goal of this survey is to collect information from as many as 150 laboratories currently performing molecular testing.

Preliminary Findings

EAC released its preliminary findings at the **American Association of Clinical Chemistry** (AACC) meeting last week in Philadelphia. "To date, we've contacted 51 laboratories now performing molecular diagnostic testing," stated Mark Hughes, Senior Consultant at EAC. "Each laboratory answered questions about the types of testing they perform, along with volumes, methods, and equipment. Their answers give us an early look at the 'state of the industry' for molecular diagnostics."

The survey is gathering information about four areas of molecular diagnostic testing. They are: infectious diseases, genetic diseases, coagulation/hematological disorders, and cancer. Survey results from the first 51 laboratories reveal an interesting picture.

First, the average number of molecular diagnostic tests performed annually at these 51 labs is growing steadily, at the rate of 14% in 2002 and 15% for 2003. Of the 51 laboratories surveyed to date, 50% offer between six and 15 assays in their molecular labs, while 22% offer between 16 and 25 different assays.

In the infectious disease category, it is no surprise that Chlamydia was the most frequently performed assay. Thirty of the surveyed labs offer it, and their annual mean volume was 57,768 and the annual median volume was 7,000. Second and third highest vol-

EAC's Key Findings About Molecular Testing

IN JUNE AND JULY 2003, Enterprise Analysis Corporation (EAC) conducted telephone interviews with 51 laboratories that maintain active molecular diagnostic programs. Key findings are listed below.

Survey included 51 molecular diagnostic laboratories:
- 46 hospital-based
- 4 private laboratories
- 1 military/armed forces lab

Survey covered these disciplines:
- Infectious diseases
- Genetic diseases
- Coagulation/Hematological
- Cancer

Key Findings:

- Molecular diagnostic labs perform an average of 15 different molecular assays.
- Overall average volume is 4,400 tests per year.
- Test volume increased 14% in 2002.
- 76% added new assays in the past 12 months.
- 80% plan to offer additional assays in the next 12 months.
- Home brew methods still used in 80% of surveyed laboratories (for at least one type of test).
- ASRs growing in popularity, with 41% of surveyed labs using at least one ASR.
- Roche is the dominant vendor, with 68% of surveyed labs using a Roche kit or ASR.

umes were HIV quantitative and HCV quantitative, with an annual median volume of 3,000 and 800 respectively.

In genetic diseases, Cystic Fibrosis testing was done at 12 labs, with a median annual volume of 500 tests. Fragile X is done at 11 laboratories, with a median annual volume of 250 tests.

Factor V Leiden is the leading molecular diagnostic test in the coagulation/hematologic category, with 25 labs performing this assay. The median annual volume is 800 tests. Next is Prothrombin II, performed at 23 labs, with a median volume of 600 tests.

In the cancer category, EAC reports gene rearrange (bcl-1, bcl-2) as the most frequently performed test. Eighteen labs offer it, and the median annual volume is 240 tests. Second and third on the cancer test list are Her2/neu (eight labs) and BCR-ABL (15 labs), with median annual volumes of 120 tests and 118 tests respectively.

Survey of Methods

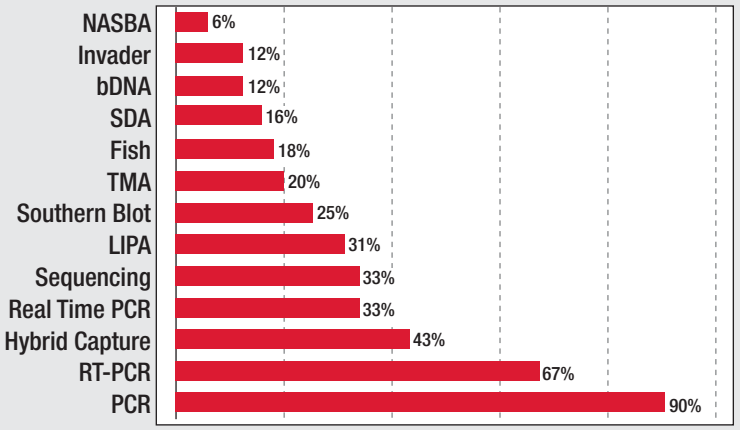
PCR is the most frequently used method, with 90% of the surveyed labs utilizing it. A majority of molecular laboratories, 80%, perform home brew assays, while 41% of the laboratories work with ASR-based assays (analyte-specific reagents).

Not surprisingly, EAC found **Roche** to be the leading vendor in the molecular diagnostics field, with 68% of surveyed labs reporting at least one Roche assay on their molecular test menu. Next was **Bayer**, with 41% of the labs using at least one assay, followed by **Digene** (37% of labs), and **Gen-Probe** (33% of labs).

"Four common issues in molecular diagnostic testing were identified from the survey," stated Hughes. "First, molecular labs want better automation solutions. Current methods are consid-

Molecular Methods and Instruments in Use

Percent of Molecular Labs Using Various Methods



Note: Others mentioned include RFLP, ARMS, LLA, gel detection and direct probe.

Manufacturer's Equipment Installed in Molecular Diagnostic Laboratories

Manufacturer	Instrument	# Labs	Percent
Roche	Cobas Amplicor	26	51%
ABI	DNA sequencers *(all models)*	21	41%
Roche Digene	Light Cycler	19	37%
Bayer/Visible Genetics	TruGene System	12	24%
BD	Probe Tech	8	18%
Bayer	Quantiplex	8	16%
Roche	Cobas Taqman	6	12%
bioMerieux	NucliSens	3	6%

Source: Enterprise Analysis Corporation, Stamford, Connecticut

ered to be quite labor intensive and too slow. Second, both the recruiting and the training of qualified personnel is a challenge.

"Third, it was often stated that reimbursement levels for molecular tests are low," he added. "Fourth, budget constraints and the lack of resources was mentioned."

Those interested in tracking the progress of this survey can reach EAC at *www.eacorp.com*. This report on the responses from the first 51 molecular diagnostic laboratories surveyed provides a useful look at how early-adopter laboratories are establishing their molecular testing programs. TDR

Contact Mark Hughes at 203-348-7001.

First-Ever U.S. Use of ISO-9000 in Total Lab Design!

Kaiser Permanente NW Incorporates ISO-9000 In Regional Lab Design

CEO SUMMARY: *After achieving its ISO-9000 certification, Kaiser Permanente Northwest's laboratory division accomplished another distinction. It became the first lab in the nation to use the principles of ISO-9000 to design, build and operate a new, state-of-the-art, automated laboratory facility. The unique workflow designed into this laboratory startles visitors. Not only is this the first laboratory designed, from the ground up, by an ISO-certified lab management team, but it provides a fascinating peek at how the next generation of clinical laboratories may be designed and operated.*

Part One of Two Parts

RECENTLY THE LABORATORY DIVISION of **Kaiser Permanente Northwest** (KP-NW), based in Portland, Oregon, designed, built, and brought into operation a new, state-of-the-art, automated regional laboratory.

This laboratory facility is unique. To the knowledge of THE DARK REPORT, this is the first laboratory facility in the United States that incorporates the management principles of ISO-9000 in the laboratory's design, construction, and subsequent daily operation.

Alone, that fact makes this laboratory noteworthy. But being first is not the most important part of this story. Prior to constructing their new automated regional laboratory, the KP Northwest lab team used ISO-9000 principles to re-engineer almost every aspect of laboratory operations. The new lab facility was then designed to support the re-engineered work processes.

Lab Gained Multiple Benefits

THE DARK REPORT believes this is the most important management insight. KP-NW's lab team used ISO-9000 to create a break-through laboratory design—one that impresses senior laboratory administrators who tour the facility. As a result, when the new core laboratory became operational, its re-engineered work flow generated multiple benefits. Lab quality increased, as did productivity. Costs were reduced significantly. Morale and enthusiasm among lab employees soared. More importantly, the new automated regional laboratory provides a foundation to sustain ongoing operational improvements for years to come.

And it is these outcomes which impress knowledgeable visitors. Kaiser Permanente Northwest's new automated laboratory facility is actually a prototype for how clinical labs will be designed and operated in the future—at least those which incorporate the management principles of ISO-9000, Lean, Six Sigma, and similar quality systems.

The lab management lessons from this groundbreaking project will be explained in two parts. In this installment, THE DARK REPORT assesses how laboratory administration at KP-NW engaged its entire lab staff to help: 1) identify work process improvement opportunities; 2) apply such opportunities to the design of the new lab facility; and 3) participate in reorganizing job responsibilities necessary to implement the work flow redesign suggestions.

In the next installment, THE DARK REPORT will evaluate the actual operation of the new laboratory. There were setbacks along with the successes. But the performance numbers tell a compelling tale. For KP Northwest's lab division, effective deployment of ISO-9000 management principles generated substantial clinical and financial benefits. And the performance of the new lab to date indicates that additional benefits will continue to flow for years into the future.

New Lab Facilities' Genesis

The effort to build this new laboratory facility started almost ten years ago, in 1995. "At that time, our laboratory team recognized the need to be proactive on two fronts to support our parent organization," stated Dixie McFadden, KP-NW's Administrative Director of Laboratories. "We believed a new lab facility would allow us to advance on both fronts.

"First, we considered laboratory automation to be a tool which could help us stay competitive in our marketplace and better perform for our clinicians and members," she explained. "Second, we thought that a well-designed new lab facility would fundamentally change our cost structure for the better. It would allow us to make the same labor pool more productive.

"It would also add capacity, support the modest lab outreach program we have, and

Kaiser NW Lab Strives For "High Performance"

DESIGN AND CONSTRUCTION of the innovative new regional regional laboratory at Kaiser Permanente Northwest (KP-NW) was the result of a unique collaboration between senior administration, laboratory management, and the entire laboratory staff.

"As part of our strategic effort to achieve high levels of performance, we've substantially boosted quality and productivity in the new laboratory," stated Dixie McFadden, Administrative Director of Laboratories at KP-NW, located in Portland, Oregon. "However, this radical reengineering of traditional laboratory work processes, supported by the construction of a unique automated regional lab facility, could not have happened without the support of the entire laboratory staff. At every step, there has been close interaction with all levels of staff in the laboratory.

"For starters, the entire Kaiser Permanente organization has been developing a different working relationship with its labor partners—one based on mutual respect," she continued. "That directly affects our laboratory division, where we have two unions and four bargaining units.

"The extensive redesign of work flow in the laboratory changed the job descriptions for almost all of our people," noted McFadden. "People issues were one of the most challenging aspects of operating this new regional laboratory. Communication has been constant among all our partners. The entire staff was encouraged to participate in the design of the facility and how it would be operated. We consider the enthusiasm of the staff—which has continued since the new lab facility opened—to be evidence that this collaborative process did meet the needs of most individuals."

position us to service higher testing volume as Kaiser's membership continues growing," she noted."

"We were told 'no' by administration several times," recalled McFadden. "But we believed a new lab facility was the way to go. So we would rework our proposal and try again. Eventually we received authorization to proceed with the design and construction of the new lab facility.

"Meanwhile, during this same time, our lab management team had been looking at the organization and the processes in our 15 laboratory locations," she said. "We realized that each lab site had similar equipment, did similar tests, and often times shared some of the same staff. Moreover, they were serving the same members, who were often served at different Kaiser locations.

"Despite these operational similarities, there were large variations in how they operated. We didn't have consistent lab system processes and practices across all of our regional sites," observed McFadden.

Eliminating Variation

"Strategically, it became a goal to rectify this situation," she noted. "Knowing that **Quest Nichols Institute** had achieved this outcome as part of its ISO-9000 certification, we invited George Pounds to visit our lab. Another individual we brought in was David Navilanen. Among other insights, they helped us understand how GLP (good laboratory practices) could help eliminate variation in the way our regional lab sites operated."

Exposure to the management principles of ISO-9000 had an unexpected impact on the thinking of KP-NW's lab administration. "We learned that establishing system-level documentation of work processes was just one slice of overall work flow through the

laboratory," said McFadden. "It evolved rather naturally that we should analyze and address improvement opportunities across the entire spectrum of lab operations.

"To accomplish this, during 1998 and 1999, we underwent a 'gap analysis' with the help of consultants familiar with ISO principles," explained McFadden. "We found that, in some areas, GLP had pushed us far along. But other operational areas of our labs needed lots of work. The decision was made to pursue ISO certification.

ISO-9000 Certification

"By October 2000, **GS** (International Certification Services) successfully conducted an audit of our regional laboratory, which led to that lab's ISO-9000 certification. Although not ISO-certified, our other regional lab sites operate under ISO principles and share standardized work instructions."

Even as work on ISO certification was occurring, there was progress on the request to build a new regional lab facility. "In the fall of 1999, KP administration issued conditional approval for us to proceed with the design and construction of a new automated laboratory," stated McFadden. "Final approval was issued in February 2000, right in the midst of our efforts to gain ISO-9000 certification."

With that approval, formal planning to design the new lab began in April 2000. "Because we were now trained in the principles of ISO, we wanted to design our new laboratory facility to reflect those techniques. We knew we wanted three things: automation, a lab without walls, and a layout that would support ongoing, systematic redesign of of workflow through the lab," summarized McFadden.

"Twelve people made up the conceptual design group, including pathologists, Ph.D.'s, managers, a national facilities representative, and our consultant," she noted." In June, following two months of conceptual work, 15 design teams were initiated, consisting of lab staff members.

"Each design team had a project leader," continued McFadden. "Some were managers and some were staff members. Kris Bailey (AICon consultant) was the project director who coordinated this effort. Carol Vogt, KP-NW clinical service manager, was the project manager throughout the two-year process.

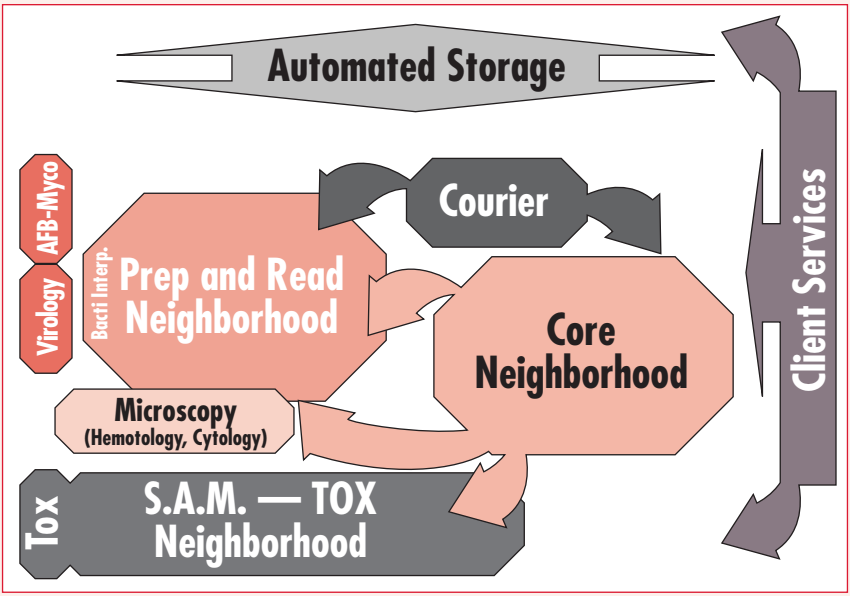
"There were 15 design teams. Each team was trained in ISO system documentation and workflow design techniques," noted McFadden. "This training meant that our teams now looked at laboratory operations through a 'new' lens—one that emphasized systems and processes. Each team performed workflow mapping, did physical design of their area for the proposed lab, and specified necessary equipment."

"Whereas most people design a new laboratory by department, we did not!" declared McFadden. "Using insights from ISO, our 15 teams designed our new regional lab by process and by volume."

McFadden says the "aha moment" came early in the design process. "We mapped our existing work processes, then laid them out on the floor plan of the proposed new lab facility," she noted. "We recognized that the same work process occurred in five separate places around the lab. Logically, all this work could be put in one place in the lab. The new work area that was created is called 'shared preparation.' This includes specimens for histology, cytology, microbiology, special chemistry, and anatomic pathology."

ISO Principles Drive Unique Design For Kaiser NW's New Regional Lab

This early concept diagram shows how designing by volume and process broke down traditional lab departments



Given the rare opportunity to design and build a state-of-the-art automated regional laboratory from the ground up, Kaiser Permanente Northwest Laboratories created a radically different facility, unique in the United States. The new lab's design is a direct result of the application of the management principles of ISO-9000. The concept diagram shown above demonstrates how the facility was organized around functions and like work processes, not traditional laboratory departments. The concept of "neighborhoods" reflects this unique approach, which puts similar work processes together in one area, even if it involves different types of laboratory tests.

This design breakthrough represented a fundamental difference in how the new KP-NW lab facility was designed. "Whereas most people design a new laboratory by department, we did not!" declared McFadden. "Using insights from ISO, our 15 teams designed our new regional lab by process and by volume."

Such design innovations quickly led to the dismantling of traditional laboratory departments, since the goal was to design around process and function. "Another key innovation came from a staff member," recalled McFadden. "She said, 'since we are not departments anymore, maybe we are neighborhoods?' That term caught on. Now we have neighborhoods for Medical Offices, Hospital Lab, Core Lab, Prep and Read, SAM/TOX, Client Services, and Support."

In creating the radical changes found in the new lab facility, the design teams started with existing laboratory work flows. "It was as simple as starting with a map of the existing work area in our exist-

ing lab departments," said McFadden. "Once this was done, design teams then applied ISO tools to create smoother, more efficient workflows in the new lab. It was at this stage that a cascade of innovations occurred.

"It was remarkable to see the creativity and clever solutions which emerged from the design teams," she added. "Because people from all parts of the lab were part of the design process and were designing their future work environment, they had a high level of commitment and recognized how specific changes would benefit the lab and allow them to make a greater contribution. Their design recommendations were so comprehensive that we saved a considerable amount on architectural fees—and got a better-designed lab facility!"

Notable Achievement

The innovative new regional laboratory at KP Northwest is a significant event for the laboratory industry. It is the first sizeable laboratory designed, built, and operated by an ISO-9000-certified laboratory organization.

It means this laboratory is the first real-world demonstration of the quality management systems in use throughout commerce and industry, but still relatively untried in healthcare. For that reason, its successes and its failures merit closer study. The second installment in this two-part series will address these topics.

One noteworthy lesson about the design phase of this pace-setting laboratory facility should be obvious: Once laboratorians are trained in the principles of quality management, they gain a new set of useful tools. It helps them understand lab operations and outcomes in new ways. Not only do they have a deeper understanding about the systemic cause of problems, but they have a new set of tools with which to identify and fix those problems.

In designing the KP-NW regional lab facility, it was the lab staff themselves who recognized that five separate departments currently performed the same accessioning function—and that this function could be consolidated and handled in just one area of the laboratory. This same concept of combining similar work processes, even across traditional department lines, led to the concept of "neighborhoods."

In many lab environments, concepts such as these would certainly represent radical changes. Lab staff with decades invested in defending their department from various types of re-engineering efforts, would vigorously oppose the creation of neighborhoods organized around lab function, not test menu.

Yet, within the labs at KP Northwest, virtually the entire lab staff contributed to creating new neighborhoods, then participated in the process required to staff these neighborhoods. That unusual support for a radical reorganization hints at the positive downstream benefits that accrue from using quality management principles to re-engineer an existing laboratory.

Perceptive lab directors and pathologists will pick up on this. For these individuals, a site visit to the KP-NW regional lab facility can offer valuable insights about how to successfully deploy quality management systems in their own lab organization. TDR

Contact Dixie McFadden at 503-258-6823.

COMING IN PART TWO

How Unique Work Flow Design Enhances Quality & Productivity at Kaiser NW's New Regional Lab

Includes a look at automation's impact, automated inventory, implementation successes and setbacks, impact of creating new job descriptions for virtually all lab personnel, and an assessment of lab management lessons learned.

Behind The News

AACC and CAP Meetings Generate Useful Insights

Timely intelligence on a variety of trends emerges at both national gathering

IT WAS A BUSY TIME LAST WEEK on the lab industry meeting circuit. THE DARK REPORT made the rounds and uncovered some valuable intelligence for lab directors and pathologists.

First on the meeting tour was Philadelphia, site of the **American Association of Clinical Chemistry** (AACC) annual convention, held July 21-25. The number of exhibitors and the size of the exhibit hall was equal to earlier conventions. However, in contrast to past years, the AACC did not regularly announce the number of attendees over the public address system. Speculation was that attendance was down this year. The most obvious cause may be concerns over terrorism and the Middle East situation which discouraged international travel to Philadelphia.

Looking For New Trends

Nonetheless, as many as 15,000 attendees and vendors were present, along with lots of interesting new technology and products. Taken together, it was an opportunity to identify new trends and validate existing trends.

On the laboratory automation front, diagnostic manufacturers again emphasized modular or workstation solutions. In response to lab buyer's needs, vendors are concentrating on automating specific aspects of the testing process. For example, **Ortho-Clinical Diagnostics** (OCD) unveiled its Ortho ProVue™ instrument, which automates tests done in blood banks.

In the evolving battle between "open" and "closed" TLA systems, one emerging winner may be **LabInterlink**. At the AACC, a number of the major diagnostic vendors showed LabInterlink equipment engineered specifically to connect their instruments to an automated line meeting the NCCLS clinical laboratory automation standards.

New Interest In Automation

Talk at the AACC meeting indicates that some of the nation's largest laboratories are telling their instrument vendors that they will only buy instruments compatible with open laboratory automation standards. That gives these labs the ability to "plug and play" any combination of instruments, by any vendor, into their lab's specific automation configuration.

"Closed" automation systems will continue to be sold. But there is growing evidence that the laboratory marketplace prefers "open" system solutions. If those vendors now selling closed automation systems expand their offering of open instruments, it will be confirmation that the lab marketplace definitely supports the open option.

There is another trend in lab automation that will be relevant to lab directors and pathologists. THE DARK REPORT believes that the patient safety movement will increase interest in laboratory automation solutions. As labs come under pressure to eliminate errors and reduce variation in specific work processes, automation can be one solution to achieve both goals.

Less Errors And Variation

Manual work processes are one source of errors in the laboratory. Mechanization and automation of manual work processes is a proven way to reduce both errors and variability. For example, OCD's new Ortho ProVue instrument, mentioned above, was designed to help blood banks achieve both those goals by eliminating the manual steps required to test blood products.

It is an interesting change to the way lab administrators view automation. In the mid-1990s, automation was judged primarily by its ability to lower costs and increase lab capacity. In recent years, lab automation has increasingly become a labor-substitution solution, allowing labs to move medical technologists to higher-value uses. Now lab automation will also be viewed as a tool that helps labs reduce errors, reduce variability, and improve turnaround times and lab test quality.

CAP's Management Confab

In Chicago, the **College of American Pathology's** (CAP) "Pathology Practice Management 2003" was conducted on Saturday, July 26. This annual one-day meeting covers the full range of trends in the pathology marketplace, legislative updates, and information on evolving legal, billing, coding, and malpractice issues.

On the legislative front, there are several interesting issues which are not known to most of the lab industry. In

Clinicians Pulling Tests Out of the Core Lab

ONE CONSEQUENCE OF THE MOVEMENT to provide standardized care to all patients is that more testing will migrate from core labs into near-patient and point-of-care (POC) settings.

Evidence of this came at a press conference conducted by **Beckman Coulter Corporation** at the AACC meeting in Philadelphia last week. The topic was the laboratory's role in reducing patient errors and supporting higher clinical outcomes.

The press conference featured a panel that included THE DARK REPORT, **Baptist Hospital of East Tennessee** (which reported on how automation reduced variation and improved TAT and other clinical outcomes), and an emergency room specialist from the **University of Massachusetts Medical Center** (UMMC) in Worcester, Massachusetts.

Djiby Diop, M.D. discussed the recently established standards for cardiology care. From the moment the patient appears at the ER door, the ER has 30 minutes to start blood-thinning drugs and 90 minutes to get the patient into the cath lab, as appropriate to the patient's symptoms.

The 30-minute and 90-minute standards mean that most hospital core laboratories cannot deliver lab test results fast enough to support these standards. To meet this challenge, UMMC's emergency department has begun a point-of-care cardiology testing program within the ER.

In deciding to do POC cardiology testing in the ER, there was little debate within UMMC about issues of higher cost-per-test, quality of test results, and similar arguments put forth by lab managers wanting to keep tests in the core lab. What drove this decision was the need to support the ER's ability to meet the 30-minute and 90-minute standards for appropriate patient care. Like at UMMC, clinicians will begin to pull testing out of the core lab as a way to improve outcomes and meet standards.

her presentation, Denise Bell, Director of Federal and State Legislative Affairs for CAP, noted that the pharmacy trade association was involved in a nationwide effort to get individual states to pass legislation that would change the scope of practice and allow pharmacists to "order, perform, and in some cases, interpret laboratory tests." To expedite this effort, the pharmacy profession has model legislation it provides to state legislatures.

Turning to the pending Medicare legislation now in the House-Senate conference committee, Bell identified a provision passed by the House which has received little attention, but which could have considerable impact on the lab industry. The version of the Medicare drug benefit bill passed by the House includes a provision which supports the move away from ICD-9 and toward ICD-10. The objective is to develop a national code which would also supplant the CPT code system.

Next HIPAA Deadline

Bell also called attention to the fact that, effective October 16, all providers must comply with HIPAA requirements for electronic transactions and code sets. "This is a big event," she declared. "However, CMS (Centers for Medicare and Medicaid Services) will use a carrot and stick approach in enforcement.

"CMS will respond to complaints about non-compliance. If the non-compliant provider is making reasonable efforts to achieve compliance, CMS will not take immediate action. But if that provider, after some number of months, has not achieved compliance, CMS indicates it will take action to enforce compliance."

During her presentation on the legal issues of Part A clinical pathology professional agreements, attorney Jane Pine Wood of **McDonald Haber** revealed a new legal issue involving the responsibilities of the laboratory medical director. In the South, several hospital laboratories shared lab test proficiency data by telephone, violating CLIA regulations. This came to the attention of CMS, which investigated the matter and made an unexpected ruling.

Potential Legal Exposure

"It was a single pathology group serving the hospital labs involved," noted Wood. "Because the contract for medical directorship of the several hospital labs was held in the name of the pathology group practice, CMS ruled that all the pathologists who were members of that group were at risk for violating CLIA regulations.

"CMS has not issued a final ruling in this case, but its declared position is an unanticipated interpretation of the CLIA regulations," added Wood. "Any pathology group holding a similar hospital contract to provide medical director services to multiple hospital labs will find it prudent to review this situation. One solution may be to hold laboratory directorships in the name of individual pathologists—not the group practice itself."

Strategic Planning

Each of the insights gleaned from both the AACC meeting and the CAP program and presented on these pages represent valuable business intelligence for lab administrators and pathologists. Collectively, they identify issues which either need direct attention, or will shape the strategic thinking of laboratory leaders.

The issues highlighted on these pages also demonstrate that a wide range of outside influences continue to impact the laboratory industry. TDR

Contact Denise Bell at D.Bell@CAP.org and Jane Pine Wood at JPWood@md.com.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

In recent weeks, **Quest Diagnostics Incorporated** lost both a key executive and a major client. Vicki DiFrancesco, Vice President of Hospital Sales and Marketing, submitted her resignation earlier this month. She is leaving to pursue personal interests. DiFrancesco became part of Quest Diagnostics when it acquired **American Medical Laboratories** (AML) last year. AML had successfully captured many Quest hospital reference accounts and DiFrancesco had played a major role in that success. *(See TDR, September 16, 2002.)*

MORE ON: Quest

Within the past two weeks, one of Quest Diagnostics' largest hospital reference clients decided to switch. **North Shore Long Island Jewish Health System** laboratories (NSLIJHS) inked a new reference testing contract with **Mayo Medical Laboratories**. This health system is one of the nation's five largest, so the loss of prestige to Quest is probably as painful as the loss of referral testing and comes on the heels of DiFrancesco's departure.

CMS AND PREMIER COLLABORATE ON PERFORMANCE PLAN

CMS (**Centers for Medicare and Medicaid Services**) has been authorized funding for a hospital "pay for performance" plan that relies on clinical data gathered and stored by **Premier, Inc.** Over the three-year life of this demonstration program, up to $21 million will be distributed to participating hospitals which score in the top 10% of quality in the five clinical areas of coronary artery bypass surgery, heart attack, heart failure, hip and knee replacement, and pneumonia. Premier's "Perspective" clinical database will house the performance data.

ADD TO: Performance Plan

There is one controversial aspect to this performance-based incentive plan. That is CMS's intent to assess penalties for low performers. To aid in recovering the cost of the demonstration program, CMS plans, in year three, to cut Medicare payments by 2% for the poorest performing hospitals that show no improvement and by 1% for the next 10% of lowest performing hospitals. For lab directors and pathologists, this demonstration project is evidence that more provider measurement programs are on their way. Both clinical laboratories and anatomic pathology group practices should watch these developments and prepare appropriate strategies to respond to these types of provider measurement programs.

ROCHE PAYS IGEN $1.415 BILLION IN BUYOUT

Roche Holdings will settle a six-year long patent infringement dispute by purchasing patent-holder Igen **International, Inc.** for $1.45 billion. Roche had lost the court battle and faced a $505 million judgement. The Igen patents affect Roche's Elecsys/E170 diagnostics product line.

That's all the insider intelligence for this report. Look for the next briefing on Monday, August 18, 2003

PREVIEW #1

PATHOLOGY INCOME & EQUITY

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UPCOMING...

- ***Part Two: Kaiser Permanente NW Uses ISO-9000-Designed Laboratory to Boost Quality and Productivity.***
- ***Pathology Group Hits Financial Home Run With Doctor-Pleasing Oncology Services.***
- ***Unanticipated Exposure Creates New Regulatory Threat For Lab Medical Directors.***

THE DARK REPORT has moved to Austin, Texas.
Our new offices are located at:
21806 Briarcliff Drive, Spicewood, Texas 78669
512.264.7103 • Fax: 512-264-0969

www.darkreport.com