Volume IX, Number 9 Monday, June 24, 2002

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

Specialty Lab's Woes Trigger Big Market Shift

IT'S THE UNPUBLICIZED STORY BEHIND THE STORY. Most of the laboratory industry knows that **Specialty Laboratories, Inc.** is the target of sanctions issued by both federal and state laboratory regulators. But the impact of this development has yet to be recognized across the industry.

Published federal statutes and regulations do not clearly address Specialty Lab's unique situation. Attorneys doing independent research for Specialty and client laboratories acknowledge that laws and regulations lack clarity on the issue of Specialty's CLIA-88 license, revoked subject to a pending legal appeal. Nor is there clear agreement on how Medicare billing regulations are affected by the sanctions. There is no precedent to guide either government regulators or laboratories. That leaves the ultimate interpretation to government regulators and creates uncertainty among laboratories that refer tests to Specialty Labs.

This uncertainty over a variety of legal and compliance issues has caused a number of Specialty's customers to begin shifting specimens to competing reference and esoteric laboratories. Collectively, they are choosing a conservative course of action to comply with their interpretation of statutes and regulations. The magnitude of this shift appears to be large. A number of competing reference and esoteric labs tell THE DARK REPORT that they have been overwhelmed by requests to open new accounts. To cope, they have added staff and resources to their new account teams.

The magnitude of this customer shift will only become known when Specialty Laboratories files its second quarter earnings report. That won't happen before mid-July. However, the anecdotal stories reported recently by competing reference and esoteric laboratories provide credible evidence that large chunks of market share in this lab testing segment are shifting away from Specialty Labs.

Collectively, the preponderance of evidence says that a sizeable shift in the market for reference and esoteric testing has been occurring. It started on April 15, when news of sanctions against Specialty Laboratories became public. In just 10 short weeks, the shifting of accounts among competing reference and esoteric laboratory companies has been significant. It shows how fast the laboratory marketplace can react to unexpected events. TDR

Specialty Labs Struggles To Maintain Operations

Troubled company has new executive team that must fix regulatory and business problems

CEO SUMMARY: In April, Specialty Laboratories, Inc. disclosed that state and federal regulators had placed sanctions on the esoteric testing company, including revocation of its CLIA-88 license, subject to legal appeal. One main source of concern is the fact that, over the past 10 weeks, a sizeable number of Specialty Labs' customers have begun redirecting specimens to other reference and esoteric laboratories.

IT'S BEEN TOUGH TIMES at **Specialty Laboratories, Inc.** since the April 15 announcement that state and federal lab regulators issued multiple sanctions because of deficiencies in the lab's operation.

It's a laboratory management crises without precedent. On one hand, Specialty Laboratories faces revocation of its CLIA-88 license, subject to a legal appeal which is pending. Thus, considerable management resources must be directed to developing a POC (plan of correction) that is acceptable to the **California Department of Health Services** (DHS) and **Centers for Medicare and Medicaid** (CMS).

On the other hand, Specialty Labs must deal with a steady and significant decline in the daily volume of specimens referred by its clients. Based on rumors and comments made by departing employees, the decline in specimen volume has been significant since April 15. Calls to Specialty Labs on this subject were not returned.

If these estimates are accurate, the precipitous decline in specimen volume means an equally significant reduction in revenues. To maintain financial viability, Specialty Labs must swiftly prune back expenses. But cost reduction efforts also require significant management resources.

Thus, Specialty Laboratories is literally in the jaws of a vice. The squeeze on one side involves a plan to return to regulatory compliance. The squeeze on the other side is the urgency to slash expenses so they stay in line with declining revenues.

THE DARK REPORT Intelligence Briefings for Laboratory CEOs, COOs, CFOs, and Pathologists are sent 17 times per year by The Dark Group, Inc., 1731 Woodland Terrace Center, Lake Oswego, Oregon 97034, Voice 1.800.560.6363, Fax 503.699.0969. **(ISSN 1097-2919.)**

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).

What makes this doubly challenging is the turnover in Specialty Labs' executive ranks. On June 7, President and COO Paul Beyer resigned. He will keep his director's position on the board and the position of COO will be eliminated. About this same time, several more senior executives also left the company's employ.

Medical Director's Role

The new corporate medical director is Douglas S. Harrington, M.D., who also holds the position of Chairman and CEO. *(See TDR, May 13, 2002.)* He was elected by the board following the resignation of founder James X. Peters, M.D., Ph.D. on April 22, 2002.

As noted in earlier issues of THE DARK REPORT, Dr. Harrington has unique experience with laboratory regulators. While with **Nichols Institute** during the 1988-91 period, he developed a POC to address identified areas of non-compliance and successfully guided implementation of the POC. As corporate Medical Director of Specialty Laboratories, it is hoped that his goodwill and experience with lab regulators will help speed a return to compliance.

Daunting Challenges

By any business standard, Specialty Laboratories is a company in crisis. The list of challenges reveals the seriousness of this crisis.

First, it faces revocation of its CLIA-88 operating license. It must devote full attention to curing deficiencies and restoring the confidence of lab regulators so that this sanction, as well as the others, are removed.

Second, as the daily volume of specimens declines, Specialty Labs must slash expenses. In its own right, this is a stressful, complex management task and requires the full attention of management—even though management must also address regulatory issues.

Third, a substantial number of managers who have valuable knowledge and experience are now gone. New managers face the daunting task of learning about the company, its operations, and its customers—while simultaneously fixing all the problems.

Fourth, the magnitude of the decline in daily specimen volume means that Specialty Laboratories will not have the cash flow necessary to pay for all the corrective actions it must take. It must be assumed that the company is now in a negative cash flow situation that creates additional pressure.

In addressing this situation, Specialty announced on June 18 that it would lay off 10% of its workforce. It has also trimmed the number of tests it performs and is referring some specimens to other labs. This is one source of the decline in daily specimen volume.

A Test Of Customer Loyalty

Five, time now works against the company. Each day brings a further unraveling of its existing customer relationships. The primary value of a laboratory is its customer base, not the physical laboratory, instruments, and employees. Thus, the longer it takes Specialty to effect a solution to its current situation, the less value the company will have—either to its shareholders or to prospective buyers.

What are the options for Specialty Laboratories? Reaction of its customers to the unwelcome news of regulatory sanctions was swift. The immediate financial impact of their defection must be coupled with the fact that, over the long term, it will take years and lots of money for Specialty Labs to rebuild its client base.

In fact, the swift decline in specimen volumes may actually be causing potential merger partners or acquirers to stand aside. On one hand, competitors are gaining Specialty's clients without hav-

Loss of Reputation Triggers "Crisis of Confidence" With Huge Consequences for All Laboratories

SPECIALTY LABORATORY'S WOES provide a chilling reminder that should not be ignored by lab executives and pathologists.

Any clinical laboratory is only as good as its reputation with the public. If events cause the public to lose faith in a laboratory, the ensuing reaction can severely and swiftly damage the financial stability of the laboratory and possibly even lead to its demise.

This is certainly one possible consequence now facing Specialty Laboratories since it became public knowledge on April 15 that both state and federal lab regulators had issued multiple sanctions against the lab company, located in Santa Monica, California.

Based on what facts were disclosed, many customers of Specialty Labs have voiced a host of concerns. These include questions about the way the company has performed lab tests, whether certain specific sanctions raise compliance issues that affect laboratory customers referring tests to Specialty Labs, and even about whether the company will be able to survive financially.

Not surprisingly, these concerns have led many lab administrators and pathologists to begin directing referral testing to other sources. They are taking their business elsewhere until problems within Specialty Laboratories are resolved.

Another example of how quickly the public can become alarmed about a laboratory's problems was in April 1999. **SmithKline Beecham Clinical Laboratories (SBCL)** caused a national sensation when it admitted that a phlebotomist it employed in its Palo Alto, California patient service center (PSC) had reused butterfly needles when drawing blood from patients. *(See TDR, April 26, 1999.)*

To allay public concerns, SBCL and the California Department of Health Services notified as many as 15,000 people that they should come in for blood testing because they had visited a PSC during time periods when this phlebotomist was known to be on duty.

The story was given wide play nationally. Daily newspaper and television stories ran for weeks in the San Francisco Bay area, keeping SmithKline Beecham's name in the headlines. A number of lawsuits were filed and some may still be winding their way through the courts.

In the case of SmithKline Beecham Clinical Labs, it was recognized that the actions of this one phlebotomist were a "rogue event" and the company's business in San Francisco did not suffer greatly.

In the case of Specialty Laboratories, the story is still unfolding. As its customers redirect specimens to competing labs, it remains to be seen whether Specialty Labs will have the financial staying power to successfully deal with this crises and remain an independent laboratory company.

However, both these examples reinforce two important points. First, any clinical laboratory is only as good as its reputation. Second, that reputation can evaporate instantly, putting the laboratory in a

ing to buy them. On the other hand, likely buyers probably consider it smart to allow events to run their course. They can then make an acquisition offer to a diminished Specialty Labs. Alternatively, were Specialty to seek protection by filing Chapter 11 bankruptcy, buyers could then bid for the troubled company at that time, following a process supervised by the court. TDR

Marketing Approved Kits Against "Home Brews"

Major labs continue to aggressively market "home brew" assays against approved tests

CEO SUMMARY: In past years, it was customary for laboratories to shift away from performing or ordering "home brew" tests in favor of FDA-approved test kits as they became available. However, new marketing models for diagnostic testing are shifting this long-standing practice. HIV resistance testing is one type of testing where this battle between "home brew" and approved test kit is playing out.

IT'S AN UNEXPECTED DEVELOPMENT in the lab testing marketplace. Some "home brew" assays are failing to yield to assays which have gone through the **Food and Drug Administration** (FDA) review and clearance process.

To the contrary, labs offering home brew versions of selected assays have chosen to continue marketing those assays in competition with test kits which have undergone regulatory scrutiny and approval.

Probably the most widely-ordered home brew tests involve HIV genotyping which deferentiates HIV resistance. During the past year, **Visible Genetics, Inc.** gained FDA clearance to bring its TRUGENE™ HIV-1 Genotyping Test Kit to market. However, the arrival of this product has not stopped several national labs from continuing to aggressively market their home brew versions of HIV-1 genotyping throughout the country.

Currently, a hospital laboratory seeking to provide HIV-1 resistance typing has three options. One, it can buy a home brew version. In recent years, three important sources of these home brew HIV-1 resistance tests have been **Laboratory Corporation of America**, **Quest Diagnostics Incorporated**, and **Specialty Laboratories**. Two, it can buy the TRUEGENE HIV-1 test from a reference lab which offers this assay. Three, it can decide to set up and perform the TRUEGENE HIV-1 test in its own laboratory.

Interesting Problems

"This presents some interesting problems for pathologists," stated Michael Mihalov, Director of the Molecular Diagnostics Center at **Resurrection Medical Center** in Chicago, Illinois. "First, it makes it tougher for them to understand the level of expertise and quality they get from each different lab's home brew version of the same test.

"Second, referring pathologists don't always understand the specific methodologies used by different reference laboratories," he said. "Different test methodologies have differ-

ent clinical implications. Pathologists need to know the clinical implications of each test methodology if they are to properly support the clinicians using these test results."

Dr. Mihalov points out an interesting fact about the potential quality differences in home brew HIV resistance testing. "At the *Clinical Virology Symposium* in April this year, doctors from a lab and a clinic in California reported on a study they undertook to evaluate the quality of tests results from various versions of HIV-1 resistance typing, both home brew and FDA-approved," he noted.

Differences In Test Results

"To compare reference lab detection proficiency, the study authors first collected blood, under informed consent, from five patients with HIV-1. Under different patient names, over a period of two weeks, they submitted 10 aliquots from each patient to each of four reference labs as routine clinical samples," explained Dr. Mihalov. "For samples with a viral load greater than 1,000 copies of RNA/ml, the accuracy of reported drug resistance mutations ranged from a high of 99% to a low of 64%.

"Certainly this range of detection rates has implications for clinicians," Dr. Mihalov observed. "But I doubt most pathologists handling such test referrals would believe the variability in test results would be this great."

THE DARK REPORT observes that home brew testing has grown in scope and complexity during recent years. It was designed to allow research labs to develop new test technology. But certain lab industry experts believe that offering home brew assays to clinicians in a commercial setting stretches the original intent of existing laws.

Infectious Disease Markets

Like HIV, other common infectious diseases are seen as huge markets for a new generation of genotyping tests. In particular, HPV and HCV are expected to find widespread clinical application once they demonstrate effectiveness in guiding decisions about diagnosis, therapy, and patient monitoring. Under current circumstances, the lab industry may see

HIV Resistance Testing Involves Several Steps

PHYSICIANS TREATING AIDS PATIENTS use three basic diagnostic tools to proactively manage their patients.

"The first step is to measure the quantity of HIV virus in the patient," stated Michael L. Mihalov, Medical Director of Laboratories at Resurrection Medical Center in Chicago, Illinois. "Most labs use the Roche assay to perform this test.

"Typically, viral load tests are done several times per year on an AIDS patient," he continued. "It is common to also measure immune system status using the count for CD-4 and CD-8 lymphocytes. A flow cytometer is frequently used for this test.

If the patient's viral load is increasing, the physician can test to determine what types of drug-resistant mutations have developed. Besides the Visible Genetics TRUGENE HIV kit, there are home brew assays available which use genotyping or phenotyping to identify drug-resistance strains," explained Dr. Mihalov.

"Our hospital laboratory is set up to perform the TRUEGENE HIV-1 test," he noted. "We can pay a minimum of $450 to send out these specimens. We calculate our cost to do the test in-house is about $275.

"However, what is more important than cost is our expertise and control over the test methodology," added Dr. Mihalov. "TRUGENE also has an interpretative section on the test report which is generated by a rules-based software program that is regularly updated by a panel of physician-experts as well as a 24/7 help desk."

home brew test versions for these diseases selling in the marketplace along with FDA-approved test kits.

There's a simple reason why laboratories offering a home brew HIV-1 resistance test have not shifted to using the FDA-approved TRUEGENE HIV-1 kit. Home brew tests are significantly more profitable to these labs than buying a kit from Visible Genetics. The public lab companies offering home brew HIV resistance testing are unwilling to take the revenue hit that would occur when they set up and begin offering the Visible Genetics' version of the test.

Not surprisingly, these national reference labs maintain that they have proprietary expertise in their particular version of HIV-1 resistance testing they offer clinicians. However, to date, none of these lab companies has opted to submit their home brew recipe to the FDA for review and clearance.

Encouraged Access

Until the FDA approved the Visible Genetics test for HIV-1 genotyping in 2001, the only source of HIV resistance testing was home brew testing offered by a handful of laboratories. Under those circumstances, regulators would have found it politically troublesome to restrict access by AIDS patients to the types of tests which are becoming integral to managing their disease.

However, the arrival of an FDA-approved test kit for HIV-1 resistance typing begins to change that situation. Now a diagnostic test that has undergone the FDA approval process is available to compete against home brew tests. Because the FDA has a charter to "protect the public," it is possible that officials within the FDA would: 1) consider an assay that had undergone the FDA review and approval process to be a "better" product than a home brew version of the same type of test; and, 2) as regulators, they might have liability, either political or legal, from taking no action on the issue of home brew testing.

Many lab administrators and pathologists recognize that a regulatory battle over home brew testing is taking shape. Intuitively, it is understood that active commercialization of tests developed under the home brew exception moves past the original intent of these regulations.

Maximizing Test Integrity

FDA regulators will probably get lots of support from the diagnostics industry should they move to further restrict the use of the home brew exemption by commercial laboratory companies. After all, diagnostics manufacturers pay substantial amounts of money to meet FDA regulations designed to insure standardized protocols for approved tests with reagents manufactured under GMP (Good Manufacturing Protocols). If all this effort and expense is to maximize the integrity of test results which are reliable and reproducible, then why should commercial laboratories be allowed to aggressively market home brew tests which have not met those same criteria?

Evolving Business Model

In recent years, a number of national reference and esoteric laboratories have given greater emphasis to developing home brew tests, then marketing these tests aggressively to clinicians. This is an evolving business model and relies on a specific interpretation of existing statutes and regulations.

However, the very growth of this business model may well motivate Congress or regulators within the FDA to decide to change these regulations. This would make it tougher for a lab to "commercialize" an assay developed under home brew guidelines. **TDR**

Contact Michael L. Mihalov, M.D. at 773-752-5046.

Lab Management Update

Employers Ready To Push Hospitals, Docs On Quality

FOR THE SECOND TIME THIS YEAR, an influential group of large employers has publicly declared its intent to push hospitals and physicians to do more to improve the cost and quality of healthcare.

On June 10, the **Midwest Business Group** declared that it was time for companies to "crack down on medical costs through the same quality control techniques they employ on the factory floor." It is telling companies that they should "agressively tell hospitals and doctors how to run their operations."

Lab administrators and pathologists should carefully understand the ramifications of this development. The nation's big corporations, which for almost two decades have relied on Deming-based quality management methods to reduce costs, improve quality and better serve customers, are ready to demand that providers adopt these same management methods.

Quality Management

This is no surprise to clients and regular readers of THE DARK REPORT. Since our inception almost eight years ago, we've been unwavering in our conviction that quality management principles have a preeminent place in clinical laboratories and pathology group practices. Throughout these years, THE DARK REPORT has told the stories of numerous early-adopter labs which successfully used these management principles to slash costs, boost lab quality, and increase net profits.

The Midwest Business Group, which includes **Bank of America**, **Ford**, **General Motors**, **Kraft Foods**, **Sears**, and **3M**, is responding to the double-digit increases in annual healthcare expenses. With costs growing by 12% to 18% per year again, these companies are ready to place direct pressure on hospitals and physicians.

Employers Taking Action

The actions by this employer group are consistent with those taken by the **Leapfrog Group** in January. *(See TDR, January 28, 2002)*. The theme is the same: employers, as buyers of healthcare, are ready to tell vendors (hospitals and physicians) how to manage their businesses.

It will be simple. If, for example, hospitals in Chicago want to provide care to employees of Sears, they will have to demonstrate to Sears that they are implementing quality management methods that: 1) accurately measure the quality and cost of care; and 2) allow them to deliberately and successfully reduce costs while boosting quality.

THE DARK REPORT believes this is a major trend. More importantly, it will have immediate impact. During the next 12 months, there will be specific examples of employer/provider collaborations designed to implement quality management methods.

Hospital labs and pathology groups seeking competitive advantage would be well-advised to closely track this trend and be ready to respond when local employers begin these types of discussions with health systems and hospital administrators. TDR

CEO SUMMARY: It's a laboratory regionalization project without precedent because of its worldwide scale. Within the Armed Forces, laboratorians are working to seamlessly integrate laboratory test data generated by laboratories within the Army, Navy, Air Force, and Veterans Administration. LOINC is the tool used to link participating laboratories. The eventual goal is to create a universal medical record for all American service personnel and their dependents.

GOAL IS UNIVERSAL MEDICAL RECORD FOR ALL SERVICES & VA

Military Labs Creating Global Lab Test Data Pool With LOINC

EDITOR'S NOTE: This is the first of a two-part feature on how pioneering laboratory organizations are using LOINC (Logical Observation Identifier Names and Codes) to standardize laboratory test data on a major scale.

BY JUNE SMART, PH.D.

THREE YEARS AGO military laboratorians launched the ultimate laboratory regionalization program, one that involves all laboratories in the American military system and **Veterans Administration** across the globe.

This ambitious undertaking is built around a simple goal: to create a unified laboratory system, using LOINC (Logical Observation Identifier Names and Codes), so specimens could be referred to any laboratory worldwide operated by the Army, Air Force, Navy, and Veterans Administration. Because referred testing is a part of this project, **Laboratory Corporation of America** and **Quest Diagnostics Incorporated** are also participating.

Importance Of Lab Test Data

"Since acronyms are integral to military operations, the lab data integration part of this project is known as G-LIT (Global Laboratory Interoperability Project)," observed Thomas A. Robillard, Colonel, U.S. Air Force and Flight Commander of Pathology and Clinical Laboratories at Keesler Air Force Base in Ocean Springs, Mississippi. Robillard is one of the leaders of the G-LIT initiative.

"Because of its unique mission, military medicine has specific needs," noted Robillard. "Not only are service personnel moved anywhere in the world on short notice, but they may often find themselves in harm's way. To do the best possible job, military medicine is working to develop an electronic medical record for every serviceman and dependent that will literally follow these individuals anywhere they travel."

Like their counterparts in civilian medicine, military planners quickly recognized that laboratory test data is the major part of most people's medical record. Thus, to create a complete and accurate electronic medical record, a major first step was to develop a way for each laboratory operated within the military to feed lab test data to a central repository in a universal format. As primary reference testing sources, LabCorp and Quest Diagnostics must also have that same capability.

"The military's effort to develop an effective electronic medical record is quite complex," stated Gregory Craigmiles, Captain, U.S. Navy, Medical Service Corps, **DoD Center for Clinical Laboratory Medicine**, Rockville, MD. "There are approximately 23 'eGov' initiatives being pursued as government-wide objectives. The Office of Management and Budget assigned each initiative to a 'managing partner' department or agency.

"The Department of Health & Human Services (HHS) was designated as managing partner for the 'Consolidated Health Informatics' eGov initiative, or 'CHI'," he continued. "HHS identified the Centers for Medicare & Medicaid Services to lead the work. The Department of Defense is one of several lead partners in this initiative, along with the Department of Veterans Affairs, National Institutes of Health, Centers for Disease Control and Prevention, and Indian Health Service. The laboratory goal in this initiative is to standardize laboratory test results, successfully operationalize the process, maintain a high level of security for the data, reduce costs, and increase efficiency."

"LOINC, with its universal identifiers for laboratory and other clinical observations, was chosen to be the standard for lab test data files," explained Craigmiles. "HL-7 was selected as the electronic interface format standard and the CHCS generic interface system is used for data encryption. When we started on this initiative we had no idea of the complexity and size of the LOINC files. For instance, the LOINC master index currently con-

Using SNOMED To Map Anatomic Path Tests

STANDARDIZING TEST NOMENCLATURE for anatomic pathology and microbiology procedures are the most complex part of the military's lab test standardization project.

Mapping AP procedures is proving to be the biggest challenge and Robillard's team has not set a date for when this effort will begin. "This will be an even bigger undertaking than the clinical side," explained Air Force Colonel Thomas A. Robillard. "Presently most of our larger lab sites use SNOMED codes for all aspects of the specimen, whereas the smaller sites use only ICD-9 codes. We are still evaluating how to standardize our AP informatics. However, we may convert all the sites to SNOMED and utilize that as the initial process and later integrate SNOMED with LOINC."

Microbiology is a different story. "So far we've got a 70% success rate in mapping micro," stated Robillard "But its complexity forced us to engage microbiology specialists to help us map the micro LOINC codes.

"To get a final answer, many micro procedures must scale down through numerous levels," added Robillard. "As well, the specimen may contain more than one organism, so this can get pretty complex. Negatives are easy; it's the positive results that take lots of discrete steps, such as the separate steps needed to evaluate antibiotic susceptibilities. Computer interfaces are harder with microbiology. And don't forget we must cross all 103 sites and the private sector labs."

tains 30,598 standardized names and codes for tests and clinical measurements descriptors.

"In our project, we have mapped about 6,100 LOINC codes to about 8,600 standard test file records in CHCS," he continued. "We utilized the most commonly-used descriptors, as we wanted to make it easier to manage. The level of complexity as well as the use of the multiple legacy LIS systems proved to be an eye-opening experience."

Informatics Consultant

"Corporate help for this government project has been considerable," said Robillard. "**Science Applications International Corporation** (SAIC) modified the software for us from the original Composite Healthcare System of the DOD and also the software from the Decentralized Hospital Computer Program of the VA. This then provided us with a common base to work from. In working with SAIC, LabCorp, and Quest Diagnostics, we've discovered a common agreement among the government and the private sector about the necessity to standardize the healthcare process. That common purpose helped make headway on our lab data standardization project."

Colonel Robillard spoke on LOINC and the military's lab regionalization program at the *Executive War College* in May 2000. Since then, his team has made considerable strides in the laboratory standardization program. "We are currently doing simulations of integrated lab test data feeds from multiple labs by using mirror images of data in the system," observed Robillard.

Alpha Testing To Begin

"By this fall, we should to be ready for alpha testing with live data. We will have the capability to validate our LOINC code mapping and see it in action. This will involve laboratories at least seven sites across several states," he continued. "Our criteria was to include large laboratories with smaller feeder sites, like several mini-networks. All military divisions and the VA are represented, allowing us to check the accuracy of data flowing back and forth within the networks and across services, covering about 2,000 lab tests.

"The seven lab sites we select for the alpha test of our LOINC project will involve about three million tests per year," said Robillard. "When we fully implement this system in all participating labs, we anticipate handling about 45 million tests. Keep in mind that this is only clinical pathology and each test may have numerous descriptors."

The impending live test represents the fruits of two years labor by Captain Craigmiles and his team. It's been a massive effort to standardize all laboratory files and map them using the LOINC nomenclature. Standardization mapping is 70% complete.

Lots Of Resources

"LOINC provides a good tool for mapping lab test files," noted Craigmiles. "But it required considerable resources to get to our current mapping level. Mapping lab tests through LOINC would have gone faster had we been able to start off with a new computer system," added Craigmiles, "but we had to use the legacy systems already in use at 103 lab sites in the United States and other countries.

"This project proceeded in several steps," he continued. "First, the DoD team developed the Laboratory Standard File and submitted it to SAIC. The Standard File provided laboratory test order names and associated LOINC component result descriptors for use by all DoD laboratories. SAIC modified CHCS to incorporate the Standard File and required LOINC fields. Second, SAIC, working with the individual sites, performed a system-wide conversion to implement the Laboratory Standard File. The next step will include validation of the Standard File and mapped LOINC components during the upcoming G-LIT alpha test.

"We've mapped several different types of tests. It's required many talented laboratorians in our DoD labs who volunteered their time to get us to the point we are today. Chemistry and hematology were a snap compared to microbiology. Some of the immunology and cell marker tests hepatitis panels were more time consuming, as were the more complex molecular tests.

Mapping Across Labs

"When you have to map across the test catalogs of all laboratories and ensure they are identical, that is where the labor needs climb at a logarithmic pace," noted Robillard noted."We didn't track time on this project with precision, but we did have eight people working full-time on this project and several of them put in many extra hours. Lots of correlations had to be done between different labs to validate that we had accurately mapped their test catalogs.

"Even though we are 70% complete, we must do ongoing updates to include the many new tests released every month," added Robillard. "Another problem is that LOINC does not have codes for all the new tests in proteomic and genomic testing. To address this, the DOD works with Clem McDonald, M.D. of the **Regenstrief Institute** in Indianapolis, Indiana to add new codes to the system. He is Chairman of the LOINC Laboratory Committee."

Standardized Lab Data

"Progress towards our goal of standardized laboratory test data has been steady," stated Craigmiles. "We finally have a system in which each lab result record will have a standard analyte name, measured property, timing, type of sample, type of scale, and methodology (where relevant). LOINC provides for all these parameters, and is very specific.

"We anticipate that this is the base for future data mining," he continued. "Present data mining is problematic as

there is no true standardization when crossing data across several laboratories. Our vision is to be data mining our global laboratory records within three to five years."

Besides the obvious benefits if supporting a universal patient medical record, the military's G-LIT project will generate sizable labor savings and a reduction of errors. Robillard and Craigmiles expect labor savings will come from order entry, billing and re-keying of information. Such savings should become measurable within six to 12 months. Increased consistency with file maintenance will also be a big improvement.

Additional Benefits

There has been one unintended management consequence from this LOINC project. "When you define your computer files, you are also defining your business practices," stated Robillard. "As a result, we've gained new insights into our own lab organization as well as that of the commercial laboratories. This is pointing us to new areas of improvement.

"Moreover, as our labs begin to speak the same language of LOINC, we expect reductions in testing," he added. "This will reduce lab test costs. In particular, as a serviceman goes from one location to another, the physician will have a better understanding of what tests have already been completed. This is particularly useful in the more complex testing areas such as hepatitis and molecular testing.

More In-House Testing

"We also anticipate that our LOINC-based capability will allow us to bring more testing in-house," Robillard predicted. "Our hub labs will be better positioned to service smaller labs in our system. All this will mean savings for the U.S. government. We don't have the numbers yet, but we will closely monitor the savings."

Second phase projects include the concept of one central repository for all laboratory records. "This is still a few years into the future," offered Robillard. "But we have started work on OOT (Object-Oriented Technology) as a way to bring all the clinical data together for the physician and support the fully-integrated continuum of care.

"A couple of key concepts dominate our OOT philosophy," he continued. "One, it will allow us to encapsulate procedures and data. Two, it can support polymorphisms across objects containing data. Third, all this can be associated with hierarchical relationships.

"This will be the ultimate system, and by partnering we are making these things happen," said Robillard. "The future is paperless, and LOINC and OOT are tools to help us accomplish this. As for total centralization of lab testing services across the globe, we are still in the planning stage and we may still decide to use the hub-and-spoke network system."

LOINC's Disadvantages

These are advantages of LOINC. But what about disadvantages? "LOINC currently cannot support front-end standardization," points out Robillard. "That requires requires human intervention and a learning curve to standardize the ordering selection of tests. We are training people at all 103 laboratory sites to handle this function. Because of all the cultures involved, both nationally and internationally, it can get quite complicated. Also just like the private sector, staff turnover further complicates this effort."

One of Robillard's tips for success in this whole process is to train a medical laboratory person to become an information specialist. "You need the

Lessons Learned From LOINC: Important Implementation Advice

THREE YEARS OF HARD KNOCKS and tough experience have marked the military's effort to standardize lab test data across multiple laboratory sites. Air Force Colonel Thomas A. Robillard and Navy Captain Gregory Craigmiles offer advice and lessons learned on using LOINC.

- Train a medical technologist to work on the file structure of LOINC. Get them to be familiar with the lab database and the use of LOINC
- LOINC codes are not intended to transmit all possible information about a test, they are to identify the test result. However, a message source code can be more specific; e.g. result code—blood culture; and sample—pump blood.
- Each LOINC record corresponds to a single test result. The record includes specifications for the analyte, the property measured timing, the type of sample, the type of scale (e.g. quantitative, nominal, or narrative), and method when relative. It also contains information on the amount, route, and timing of physiologic or pharmacologic challenges.
- Verify that laboratory requisitions correctly reflect what is being ordered in LOINC. By using LOINC there is more specificity of test order and this forces retraining of test ordering patterns for more specificity and "sameness" of test ordering across sites. It requires retraining all personnel in both ordering the test and data entry.
- LOINC and SNOMED collaborate to ensure a consistent, unambiguous clinical reference that uses the strengths of each. This will take significant effort to update all lab sites, as some labs may still use ICD-9 codes. Linking the two supports the goal of an integrated continuum of care.
- Limitations of LOINC are in fine details. The code will not define the instrument used in testing, fine details about the site of collection, whether stat or routine, who verified the result, the size of the sample collected or the place of testing; e.g. lab or bedside.
- Output must be intelligible for the user. Close scrutiny of the output is important, as there is significant detail in the coding, however, much of this information is not needed to make a clinical decision.
- Most file-mapping issues of laboratory procedures are most easily addressed by those that work in the laboratory, not by informatics specialists.

files built the right way the first time," he said. "It is difficult to train an informatics person to be a lab person."

The military's effort to standardize lab test data across 103 individual laboratories is ambitious, but it demonstrates that the healthcare system wants such standardization. Participation by LabCorp and Quest Diagnostics in the G-LIT program gives them a head start on this important capability.

Are other laboratories using LOINC as a path to standardization? Yes! **Mayo Medical Laboratories** and **ARUP Laboratories** are mapping their test files. North of the border, labs in British Columbia and Ontario are adopting LOINC codes province-wide. These projects demonstrate the importance of standardized laboratory test data. **TDR**

Contact Thomas A. Robillard at 228-377-6270 and Gregory Craigmiles at 301-319-0132.

Hospital Lab Initiatives

Hospitalwide ISO-9002 Status Stimulates Gains In Laboratory

AFTER 181-bed **St. Charles Medical Center** became one of a handful of hospitals in the United States to earn its certification as an ISO-9000 facility three years ago, interaction between nursing and the laboratory has improved in unexpected ways.

Located in the central Oregon community of Bend, 181-bed St. Charles is one of less than 10 hospitals nationally which operate with ISO-9000 certification. Its pioneering experiment with ISO-9000 systems has generated some surprising outcomes.

Breaking Down Silos

"Using ISO and other management methods, our administration has definitely broken down the silos traditionally found in most hospitals," stated William Railsback, Laboratory Services Leader/Manager for the two-hospital **Cascade Health Services** system. "We are proud of the high degree of interaction and collaboration found within our institution.

"Take nursing, for example," continued Railsback. "Our laboratory has developed a close collaboration with the nursing department. Each department's planning teams include members from the other department and use a common method for implementing revisions."

According to Railsback, the ISO system established an objective framework for developing and managing work processes. "It's allowed us to expand point-of-care testing (POCT) in our hospital while maintaining strict control over quality and cost," he noted. "The work systems are based on objective criteria that removes many of the subjective or emotional factors that typically accompany POCT."

One interesting effect of these systems is to isolate "cowboys" in the organization. "Because every department in the hospital understands these objective criteria, if a supervisor unilaterally implements an arbitrary work policy, the work flow processes of our hospital quickly surface that anomaly and make that individual accountable," noted Railsback. "This has greatly reduced discord and replaced it with common purpose across our departments."

Railsback says the ISO-9000 documentation has not been a burden. "Laboratories already have their procedures documented," he said. "So we were ahead on that count. Once certification was complete, it's been very manageable. Our next initiative is to move to electronic signatures as part of our hospital's effort to implement the electronic medical record and a master population index."

Next Level Of Quality

St. Charles is moving forward with its quality initiatives. "Currently we use the Malcolm Baldridge National Quality Award Criteria as our guide to the next level of performance," commented Railsback. "The emphasis is on leadership, with management playing a smaller part in our daily activities. TDR

Contact William Railsback at 541-388-7795.

Lab Industry Briefs

DIRECT-TO-CONSUMER ADS FROM MYRIAD GENETICS TO START THIS FALL

FOLLOWING THE EXAMPLE of the pharmaceutical industry in using direct-to consumer advertising to build drug sales, **Myriad Genetics, Inc.** is about to launch an advertising campaign for its predictive genetics tests.

Beginning this fall, consumers in Denver and Atlanta will see a television, print, and radio campaign touting the benefits of Myriad Genetics' BRAC-Analysis® test for breast and ovarian cancer. These will be the first-ever ads which promote genetic testing directly to the public. A number of healthcare policy experts are concerned about how these ads may impact the public.

Direct-to-consumer advertising is just one aggressive step Myriad Genetics is taking to promote its diagnostic tests. Last December, the company announced an exclusive marketing agreement with **Laboratory Corporation of America**. Under the agreement, LabCorp's 600 sales reps will market Myriad's tests for assessing the genetic risks of breast, ovarian, colon, uterine, and skin cancers.

Not only is Myriad Genetics breaking new ground with its plans to market genetic screening tests directly to the public, but it is an example of how swiftly the old market channel for new diagnostic test technology is disappearing.

Traditionally, a manufacturer would send its sales reps directly to commercial laboratories to educate them about the test. With the help of the manufacturer's reps, the local lab would market the new tests to clinicians in the area. As more clinicians began to order the test, many hospital labs would then set up the test and offer it as well.

Myriad's market strategy is based on using LabCorp's clout and market reach as a primary method to contact office-based clinicians to educate them about these diagnostic tests. LabCorp paid Myriad an upfront fee for "the right to market Myriad's products, and technology and rights to perform mutation detection tests."

Smaller regional laboratory competitors and hospital laboratory outreach programs don't have the money to pay upfront fees for the right to introduce a new test which has yet to achieve widespread clinical acceptance. As a result, one consequence of this approach to launching a diagnostic test will be to exclude smaller labs early in the market introduction cycle.

ABBOTT AND ORASURE INK DEAL INVOLVING RAPID HIV TEST

GIVEN THE POLITICAL SENSITIVITIES surrounding the availability of a rapid test for HIV-1 and HIV-2 in the United States, one way to read **Abbott Laboratories'** agreement to co-distribute **OraSure Technologies'** OraQuick® rapid HIV-1 is that Abbott hopes this small step will help it gain favor with certain federal healthcare regulators.

The new agreement calls for Abbott Labs to distribute the OraQuick rapid HIV-1 test to hospitals and physicians' office laboratories. OraSure will distribute the test to public health facilities and the criminal justice system.

In exchange for up-front fees and ongoing royalties paid to Abbott, Orasure also receives a sublicense for non-exclusive rights to use certain lateral flow patents held by Abbott.

Lateral flow technology allows a sample to flow through a test strip and show a test result at the downstream end of the strip.

As disclosed earlier in THE DARK REPORT, health officials within the Centers for Disease Control (CDC) and the U.S. military would like a rapid test capable of detecting both HIV-1 and HIV-2. However, **Bio-Rad Laboratories** holds a patent on HIV-2, which is sublicensed to Abbott, **Chiron**, and **Ortho-Clinical Diagnostics**. *(See TDR, January 7, 2002.)*

The licensing agreement used by Bio-Rad requires that each licensee approve the extension of licensing rights to additional companies. Each licensee manufactures an HIV-2 test performed in complex laboratories. To date, they have yet to authorize use of the HIV-2 patent in a rapid HIV test.

Since the CDC and the military have been publicizing their desire for a rapid test for combined HIV-1 and HIV-2, this new agreement between Abbott and OraSure may be to establish a working relationship that eventually leads to sublicensing the HIV-2 patent to OraSure for its version of a combined rapid HIV test.

THERASENSE CLEARS FDA WITH PDA-BASED GLUCOSE MONITORING

HERE'S AN INTERESTING clinical application for the Palm-Pilot type of PDA (personal digital assistant) device.

TheraSense, Inc., based in Alameda, California, reported on June 14 that it had received clearance from the Food and Drug Administration to begin selling its FreeStyle Tracker diabetes management system for the Handspring™ Visor™ PDA.

"We incorporated the blood glucose monitoring technology from our FreeStyle monitor into a module for the HandSpring Visor PDA," declared Mark Lortz, President and CEO of TheraSense.

The FreeStyle Tracker System allows a diabetic patient "to test for glucose levels and get a read-out on the PDA screen, graph and chart the results over time, review carbohydrate food lists to track their food intake, create reminders about testing or dietary choices and more." The patient can also download and transmit this data to physicians, giving them a time-stamped progression of blood glucose levels, as well as management actions taken by the patient.

THE DARK REPORT observes that this type of patient self-test device points to the growing sophistication of consumers. Manufacturers of point-of-care testing devices are investing considerable resources to accomplish two goals. First, they are teaching consumers how to manage their condition, using the diagnostic device in a clinically appropriate manner. Second, these devices allow a patient to feed lab test data back to clinicians in a timely and accurate fashion.

At current sales rates, TheraSense will book more than $120 million in revenues for 2002. This shows how fast the patient self-test market for blood glucose is growing. This opens up new opportunities for traditional laboratory organizations. But it will require lab administrators and pathologists to "think out of the box" for ways to add value to clinicians.

For example, labs should consider developing a diabetic test and management program that supports physicians treating diabetics. One intriguing aspect would be to capture the blood glucose test data generated by patient self-testing and add that to the clinical repository. Since both physicians and payers want access to that kind of information, there should be ways for labs to generate revenue from that type of information. TDR

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Competition for HPV testing just got more intense with the announcement that **Roche Diagnostics** has obtained rights to the Human Papillomavirus (HPV) patent portfolio owned by **Institut Pasteur** in France. It intends to develop an HPV test that would compete with **Digene Corporation's** HPV test. Digene currently holds a strong market position because it owns the only HPV test with FDA approval and it tests for several HPV subtypes. By acquiring rights to these HPV patents, Roche's action threw a cloud on **Cytyc Corporation's** proposed acquisition of Digene. *(See TDR, March 11, 2002.)* On the day following Roche's announcement, share prices for Cytyc and Digene both declined by about 20%.

LABCORP-DYNACARE DEAL CLEARS FTC

Laboratory Corporation of America's proposed acquisition of **Dynacare, Inc.** cleared antitrust review on June 19. Subject to several other steps, both labs expect the deal to close in the third quarter.

IBM ENTERS INSURANCE CLAIMS PROCESSING MARKET

IBM is raising the bar on automated insurance claims processing. Its first major client is **Empire Blue Cross and Blue Shield** of New York, with 4.7 million subscribers. IBM's system uses a software engine developed by **deNovis** which has the ability to "automatically read policy statements, rules and regulations, and make payments automatically." IBM and Empire to hope to dramatically reduce the cost of claims processing, estimated to run between $16 and $40 apiece. IBM is targeting Blue Cross/Blue Shield plans, government health plans, mid-market payers, and smaller self-insured health plans.

ADD TO: *Automated Claims*

The promise of automated claims processing, using the Internet, can reduce not only the cost to handle the claim, but can also reduce turnaround time. Laboratories in New York will be among the first to benefit from this service, once IBM and Empire have completed implementation. The arrival of IBM in the automated claims marketplace increases the competition for companies like **MedUnite**, a claims processing company started by several major health insurers in recent years.

COMINGS & GOINGS:

- **Labtest.com** of Midland Park, New Jersey announced that Jack Redding had joined the firm to help in the development and marketing of its browser-based lab test ordering and results reporting product. Redding was most recently Director of e-Business at **Specialty Laboratories** in California.

- **Beckman Coulter, Inc.** went outside the company and hired Scott Garrett to be President of its Clinical Diagnostics Division, effective June 17, 2002. Garrett replaces Albert Ziegler, who retired in April. Garrett has a 20-year career with companies such as **Baxter International, American Hospital Supply Corp.** and **Dade International**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, July 15, 2002.

THE DARK REPORT

UPCOMING...

- ***Why and How Hospital Lab Clients are Changing Their Referral Lab Relationships.***
- ***Anatomic Pathology's Best Business Models: What Makes the Nation's Most Progressive AP Group Practices Successful.***
- ***Best-Kept Secrets of Modular Automation: How Hospital Labs are Boosting Productivity.***

For more information, visit:
www.darkreport.com