Volume XVIII, Number 6 Monday, May 2, 2011

From the Desk of R. Lewis Dark...

THE DARK REPORT

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

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Protecting Your Lab From New Legal Threats

ASSUME, FOR THE MOMENT, THAT YOUR CLINICAL LABORATORY OR PATHOLOGY GROUP was concerned about its potential exposure to evolving legal and compliance issues. How would you guarantee that your laboratory has: 1) correctly identified new and/or emerging threats; and, 2) implemented effective protections to reduce your lab's risk?

Typically, your lab's compliance officer would contact your lab's corporate counsel. Together, they would assess new legal and compliance developments, then develop appropriate strategies designed to keep the laboratory fully protected and in proper compliance. But, as your lab's leader, how confident are you that these individuals correctly identified all the relevant threats and new legal developments that could put your lab at risk if they went unaddressed?

Here at THE DARK REPORT, we asked that same question. But we were able to do something that most of you cannot. We contacted 10 of the smartest, most experienced attorneys who maintain a high-profile legal practice in clinical lab and pathology law. We asked them to participate in a survey and tell us their choices for the five most important issues in legal, compliance, and managed care contracting that laboratories will face during 2011 and 2012.

As you will read on pages 3-8, six of these prominent attorneys agreed to participate. We collected their lists and collated them to develop a prioritized ranking of the six most important issues that will confront clinical labs and pathology groups during the next 24 months. In so doing, THE DARK REPORT has conducted the lab industry's first-ever survey of the nation's best-known attorneys who specialize in lab industry legal matters.

We are pleased to present the initial findings of our national lab lawyers survey in this issue of THE DARK REPORT. These same six attorneys are also working with us to develop a Special Report that addresses, in useful detail, how you should understand and respond to each of the six legal, compliance, and managed care contracting priorities for 2011. Look for it shortly.

Our goal in this endeavor is to give you a unique, high-level view of what your lab industry's keenest legal minds consider to be high-priority/must-act issues for this year and next. Best of all, you have early knowledge of these potential threats, along with the time to prepare your lab. This innovative legal survey is the latest example of how THE DARK REPORT keeps you and your laboratory at the front edge of the lab testing marketplace. TDR

Key Legal, Compliance Issues for Labs Identified

Survey of leading lab industry attorneys produces surprising list of top priorities for labs

CEO SUMMARY: It's a first in the lab industry. In recent weeks, THE DARK REPORT asked the nation's leading attorneys in clinical lab and anatomic pathology law to identify the most important legal, compliance and managed care issues for 2011 and 2012. Using a consensus methodology, this survey produced a prioritized list of six key action items. Several are brand new developments—such as Medicare's RAC program and the approaching era of Accountable Care Organizations (ACO). But some are familiar, such as lab test sales/marketing concerns.

FOR 2011, LABORATORIES FACE NEW LEGAL AND COMPLIANCE ISSUES. That's one important finding from an unprecedented survey of the top lawyers who serve the lab testing industry.

Familiar with the term "RAC?" You should be, as this panel of esteemed attorneys put this at the top of the list of six high priority legal and compliance issues for the laboratory testing industry. RAC stands for the Medicare Recovery Audit Contractor (RAC) program.

Private contactors authorized by the **Centers for Medicare and Medicaid Services** (CMS) can show up at hospitals, physician offices, clinical laboratories, and other healthcare providers to conduct an audit of that provider's Medicare claims. The RAC auditor is looking for improper Medicare payments—both overpayments and underpayments. The RAC auditor will be paid on a contingency fee basis, receiving a percentage of the improper overpayments and underpayments it collects from the providers it audits.

The concept behind THE DARK REPORT'S survey of high priority legal and compliance issues is simple. First, approach the eight to 10 attorneys recognized for their active and ongoing involvement in clinical laboratory and anatomic pathology matters.

Second, ask them a simple question: "For 2011 and 2012, what are the five legal, compliance, and managed care issues that you consider require full attention and action by all clinical labs and pathology groups? Third, compile these

THE DARK REPORT Intelligence Briefings for Laboratory CEOs, COOs, CFOs, and Pathologists are sent 17 times per year by The Dark Group, Inc., 21806 Briarcliff Drive, Spicewood, Texas, 78669, Voice 1.800.560.6363, Fax 512.264.0969. **(ISSN 1097-2919.)**

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SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes THE DARK REPORT plus timely briefings and private teleconferences, is $14.10 per week in the US, $14.90 per week in Canada, $16.05 per week elsewhere (billed semi-annually).

responses and develop a consensus ranking of the most important compliance, legal, and managed care concerns now pressing the laboratory testing profession.

As a fourth step, THE DARK REPORT is preparing a Special Report of the Lab Industry's Top Legal, Compliance, and Managed Care Issues for 2011-2012. In this report, the attorneys who participated in the survey are providing detailed insight and analysis for each of the six high-priority legal and compliance matters.

Labs Should Take Action

The six top issues are presented in the sidebar at right. The attorneys who participated in this survey are listed at the bottom of the same sidebar. In the intelligence briefing that follows on pages 5-8, these six attorneys who participated in the survey comment on why laboratories should be aware of these issues, and how labs should develop a strategy to ensure they are compliant and prepared.

The method of conducting a survey and producing a rank order from the consensus opinions of leading legal experts in laboratory law and compliance is a proven way to accurately identify important issues. In turn, laboratory executives and pathologists can use this rank order list of legal, compliance, and managed care matters to establish their own priorities for action by their laboratories.

Thus, although relatively short at six key issues, this list brings focus to several new developments. RAC audits are one of those, as is the pending implementation of Accountable Care Organizations (ACO) on January 1, 2012 (when Medicare is to begin contracting with ACOs).

The legal and compliance issues associated with physician adoption and use of electronic health record (EHR) systems is identified by our survey panel of attorneys as another high priority issue. Similarly, the unfolding changes in how payers cover and reimburse for molecular tests is also prominent on this list.

National Attorneys Identify Key Issues

IN THE LAB TESTING INDUSTRY'S FIRST-EVER SURVEY OF PROMINENT ATTORNEYS, six important legal, compliance, and managed care issues were identified as the most important for 2011 and 2012. These issues are:

2011-2012's Top Legal Issues

(Ranked by priority)

1. **RAC Audits**
2. **EHR Incentives and Compliance**
3. **Molecular Test Coverage and Reimbursement**
4. **Accountable Care Organizations**
5. **Lab Test Sales and Marketing Compliance**
6. **Laboratory-Developed Tests (LDT)**

In alphabetical order, these well-known lab industry attorneys participated in THE DARK REPORT'S 2011 Lab Legal and Compliance Survey:

- **Richard S. Cooper**
  McDonald Hopkins, Cleveland, Ohio
- **Hope S. Foster**
  Mintz Levin, Washington, DC
- **Rick L. Hindmand**
  McDonald Hopkins, Chicago, Illinois
- **Patric Hooper**
  Hooper, Lundy & Bookman, Los Angeles, California
- **Peter M. Kazon**
  Alston & Bird, Washington, DC
- **Jane Pine Wood**
  McDonald Hopkins, Cleveland, Ohio

It is notable that issues associated with the sales and marketing of laboratory tests was a consensus pick by this panel of attorneys. It demonstrates that, within their individual legal practices, their laboratory clients regularly deal with matters that may possibly include inducement and Medicare anti-kickback violations. TDR

—Joe Burns

Lawyers Provide Insights About Top Legal Concerns

Legal experts comment on laboratory industry's top legal, compliance, and managed care issues

CEO SUMMARY: After conducting the first-ever survey of the most important legal, compliance and managed care concerns for clinical labs and pathology groups, THE DARK REPORT asked leading lab industry attorneys who participated in the survey to say a few words about these topics. Here are useful nuggets of wisdom, advice, and insights about the specific concerns identified by the survey. Along with such new legal concerns as RAC audits and ACOs, the perennial issue of lab test sales and marketing compliance is addressed.

LAWYERS WHO PARTICIPATED in the survey of the laboratory industry's top legal, compliance, and managed care issues were asked to provide clients and readers of THE DARK REPORT with some insights about each of the priorities identified by the survey. *(See pages 3-4.)*

Be Ready For RAC Audits

Legal issue number one is the Medicare RAC (recovery audit contractor) audit program. Patric Hooper, a partner in the firm of **Hooper Lundy & Bookman**, in Los Angeles, advised that laboratories facing allegations of overpayments should file a challenge. "That's because RAC auditors often fail to support their allegations when labs challenge them," he explained.

"Remember, RAC auditors get paid a percentage of the fines they impose on labs and other healthcare providers," added Hooper. "This form of payment could create problems because it potentially could interfere with the auditor's judgment. It gives them the incentive to identify a Medicare overcharge or undercharge that might not be there.

"With RAC auditors, as is true of any audit by a federal or state agency, the most important issue is to act quickly when a letter arrives from the auditor," he emphasized. "This advice seems elementary but it is often ignored because these letters first go to a clerk or some other worker in your laboratory who may not recognize its importance. Make sure the letter gets to someone who is conscientious about responding to the letter.

"At this early stage, it's best to get a lawyer involved to help the lab prepare an appropriate response," he commented. "Sometimes labs don't respond appropriately because that job gets pushed to lower-level staff.

"During this initial stage, it's important to provide the RAC with all of the records that the lab has for that particular test and patient," Hooper said. "The lab also should ensure that it collects all the progress notes or other medical records from the ordering physicians to support the case for why the lab performed that test on that patient." *(Contact Patric Hooper at 310-551-8165 or at phooper@health-law.com.)*

Preparing for Age Of ACOs

Accountable Care Organizations (ACO) are a new priority. Peter M. Kazon, a lawyer with **Alston & Bird, LLP**, in Washington, D.C., said clinical labs and pathology groups must be prepared to make appropriate decisions any time their lab organization is asked to participate in an ACO.

"A good starting point is for pathologists and laboratory administrators to review the proposed ACO rule that federal officials issued in April," observed Kazon. "The point of an ACO is to build in quality indicators and then allow others to assess and pay for its delivery of quality healthcare.

"Only certain entities are eligible to form ACOs," added Kazon. "Primarily these entities are hospitals and physician groups. Labs are not specifically mentioned as being eligible to establish an ACO. But if there is an ACO in the lab's city, town, or region, then the labs could participate with those entities.

"In addition, few people recognize that—at least at this point—ACOs will not involve some kind of bundled payment system," he explained. "All of the players in the ACO will continue to bill and get paid just as they would normally. Physicians will be paid under the physician fee schedule, hospitals under diagnosis-related groups, and labs under the clinical laboratory fee schedule.

"But at the end of each year, officials from the federal **Centers for Medicare & Medicaid Services** (CMS) will look at whether Medicare spent less money on each ACO patient than was spent in the previous year," he said.

"For labs, the questions regarding ACOs relate to whether the hospitals in your market that are involved with forming ACOs have their own labs," Kazon warned. "If they do, then the hospital lab is likely to participate in the ACO. Independent labs will want to meet with those providers developing the ACO to make their case for doing a better job than the incumbent hospital lab is doing.

"Being part of an ACO is a good role for labs because so much of what ACOs do will be data driven," he added. "This is an opportunity for labs because labs have data to help physicians and hospitals monitor and track patients and take care of them from a preventive care standpoint before costs get too high." *(Contact Peter M. Kazon at 202-239-3334 or peter.kazon@alston.com.)*

Incentives For EHR Adoption

The next legal priority identified in the survey is the adoption of EHR (electronic health record systems) by hospitals and physicians. There are donor requirements and meaningful use criteria that participating providers must meet.

Rick L. Hindmand, an attorney with **McDonald Hopkins** in Chicago, Illinois, advised that labs must take specific steps to ensure that they comply with the rules governing incentives for electronic health record systems.

"Sometimes a physician group may approach a clinical lab about the possibility of having that lab provide financial assistance for the group to buy the EHR software and the hardware systems needed to run that software," warned Hindmand. "In that situation, the laboratory should be very careful about how it responds to such a request. Federal rules prohibit inducement to send test volume from that physician group to the laboratory in return for this financial assistance.

"The principal concern in these cases would be the Stark Law, which applies to Medicare, and the Anti-kickback Statute, which applies to Medicare, Medicaid, and other federal healthcare programs," he said. "In some cases, the lab can reimburse 85% of the cost of the EHR and the physician group would pay the remaining 15%.

"This arrangement needs to be set forth in writing and carefully structured to satisfy both the Stark Law exception and the anti-kickback safe harbor for donations of EHR

software, information technology and training," said Hindmand. "These standards will not be satisfied if the physician group makes the donation a condition for doing business with the lab, or if eligibility for the donation is determined based on the volume or value of referrals or other business generated between the parties.

"In addition, the lab must ensure that the system meets the requirements for meaningful use (MU)," Hindmand stated. "Physicians who want to get additional Medicare or Medicaid reimbursement for installing EHR systems must meet these specific MU rules." *(Contact Rick L. Hindmand at 312-280-0111, x 3215, or rhindmand@mcdonaldhopkins.com.)*

Molecular Test Coverage

Big changes are ahead for molecular test coverage and reimbursement, another priority issue identified by THE DARK REPORT'S survey. "When laboratories that are out-of-network submit claims for molecular and genetic tests, the laboratories face certain customer service and compliance issues stemming from the out-of-network balances owed by the patients," noted Jane Pine Wood, an attorney with McDonald Hopkins.

"This is a recurrent problem when an out-of-network lab submits a claim for expensive molecular and genetic testing to the health insurance plan," she said. "Often the payer prefers that the tests be performed by one of the major national labs because the national labs have preferred arrangements with that payer.

"In these instances, how the out-of-network laboratory handles any patient co-pays or deductibles can trigger compliance concerns," continued Wood. "Take the example of the patient who has very high-end testing ordered by a physician. If the lab is in-network, the patient's regular coverage might have a $200 deductible and 20% coinsurance. But if the lab that performs these test is out-of-network, the patient might have a $1,000 deductible and a 40% coinsurance for a $2,000 test.

"That is a big dollar difference for the patient," emphasized Wood. "In this case, the patient may not be able to afford to pay that bill. It is also a situation where the out-of-network lab may be inclined to waive those charges, but doing so is tricky because of the legal issues involved.

"In this instance, the lab should at least treat the patient as if he or she were in-network, but I cannot guarantee that doing so is 100% compliant with the law," said Wood. "It is also important to note that patient balances should never be waived for beneficiaries of government health plans, except for cases of financial hardship."

Wood explained how, from a claims submission standpoint, that policy can be problematic for the lab that does the test. "Let's assume that the patient has a 20% in-network coinsurance and a 40% out-of-network coinsurance" she stated. "The laboratory is out-of-network and it bills $100 to the payer for a $100 test.

"Such a scenario opens up a compliance risk for the laboratory," she added. "Let me explain. If this laboratory had agreed in advance to treat the patient as in-network, it then bills the payer for the in-network price of $100.

"The payer reimburses the out-of-network lab at $60 (with the patient making up the 40% difference with his/her co-pay)," said Wood. "But this lab will only bill the patient for $20, which is the in-network deductible that was agreed to in advance.

"However, this gives the lab a total reimbursement of $80," she noted. "In this instance, the payer could argue that the lab submitted a false claim of $100, when it really should have been $80, because that's all the lab expected to receive.

"In daily practice, payers do not often get upset about this unless: a) it has contracted with a preferred laboratory for lower rates; or b) the out-of-network laboratory is proactively advertising its waiver policy. But this example shows why labs still need to be careful about billing in these situations," she

added. *(Contact Jane Pine Wood at 508-385-5227 or jwood@mcdonaldhopkins.com.)*

Lab-Developed Tests (LDT)

Another priority issue of concern to clinical laboratories and pathology groups involves laboratory-developed tests (LDT). Hope S. Foster, a lawyer with **Mintz, Levin, Cohn, Ferris, Glovsky and Popeo LLP**, in Washington, D.C., explained that the FDA has announced that it will exercise more regulatory authority over LDTs very soon.

"For many years, the FDA has had the authority under the Device Amendment to regulate the use of LDTs," said Foster. "But the FDA has exercised its discretion not to do so. Thus, while labs have been subject to the validation requirements of CLIA, their LDTs have not been subject to FDA clearance or regulation.

"The entire lab industry is closely watching how the FDA answers two questions," she stated. "First, what is an LDT? Second, how will labs be allowed to market, promote, and bill for LDTs?

"The lab industry is closely watching what the FDA does with regard to LDTs because so many tests that labs perform are LDTs, and they have been an important vehicle for advancement and innovation," Foster said, adding that "the general feeling is that the FDA is likely to transition into regulating LDTs, starting with those that test for disease states that carry the greatest risks for patients, such as cancer and other potentially life-threatening illnesses.

"For labs, this means they should absolutely follow the CLIA validation rules because, if they are out of compliance with CLIA, they could have a major regulatory problem," she said. "Also, laboratories need to ensure that when they market an LDT, they do so in conformance with the actual clinical performance of that test."

In the meantime, until it is clear what the FDA will do, "labs should absolutely follow the CLIA validation rules because, if they are out of compliance with CLIA, they could have a major regulatory problem," she said. "Also, laboratories should be sure that they understand which tests are actually LDTs and which are not, because tests that do not qualify as LDTs do require FDA clearance. Finally, labs should get legal advice with regard to how they market and bill for these tests." *(Contact Hope Foster at 202-661-8758 or HSFoster@mintz.com.)*

Boosting Lab-Test Sales

It will be no surprise to most pathologists and clinical laboratory administrators that THE DARK REPORT'S survey of lab industry attorneys identified legal and compliance issues involving the sales and marketing of laboratory tests as a priority concern.

"When it comes to how labs market and sell lab tests, there is a large body of law and many regulations that govern this activity," stated Richard S. Cooper, attorney and Manager of the National Healthcare Practice Group at McDonald Hopkins. "Labs run at great risk if they do not understand the appropriate federal and state laws that apply to how a clinical lab or pathology group can market and sell lab tests to providers.

"I recommend that every laboratory, with the help of its legal counsel, develop formal guidelines for sales and marketing activities; conduct and document education of personnel on such guidelines; and do an ongoing review of its sales and marketing practices against any new laws, regulations, or regulatory guidance," urged Cooper. "Laboratory test sales and marketing is full of legal pitfalls and regulatory landmines for the unaware laboratory. That is why regular due diligence should be a baseline for compliance." *(Contact Rick Cooper at 216-348-5438 or rcooper@mcdonaldhopkins.com.)*

Special Report Coming Soon

THE DARK REPORT is working with these six attorneys to produce a Special Report of the Top Lab Industry Legal, Compliance, and Managed Care Issues for 2011 and 2012. *(See the list on page 4.)*

—Joe Burns

False Positive STD Tests Get News Coverage in Indy

One patient accused her husband of cheating, kicked him out of the house because of lab error!

CEO SUMMARY: After going public with the discovery that it had reported false positive lab test results for Chlamydia to eight female patients, Mid America Clinical Laboratories (MACL) found itself the subject of stories broadcast by a local television news program. The news coverage featured an interview with one irate patient who said she had assumed her husband had cheated on her and had "kicked him out of the house." This episode is a reminder that all clinical laboratories should have policies in place to address errors in laboratory testing.

In Indianapolis last month, erroneous laboratory test results for Chlamydia made the television news. For at least one patient, the false positive results of her Chlamydia test had caused unexpected stress to her marriage.

This disclosure of inaccurate laboratory test results—and the local media coverage it generated—is a reminder to all pathologists and clinical laboratory administrators of how lab errors can disrupt the lives of patients. This episode also demonstrates how news outlets quickly pick up a story about how "the laboratory got it wrong, and patients' lives were negatively affected."

It was **Mid America Clinical Laboratories** (MACL) of Indianapolis, Indiana, which admitted to the lab test errors. On April 4, 2011, MACL issued a public statement acknowledging that it had issued false positive Chlamydia test reports. Television station *6News* reported that MACL believed eight patients got the false positive results. MACL explained the source of the errors and the corrective steps it was taking to prevent similar errors in the future.

In this statement, MACL stated that "An error occurred in our molecular testing for Chlamydia that we sincerely regret. All affected patients are being credited for testing completed and have been offered reimbursement for necessary examinations with their physicians and any medications prescribed as a result of the discrepant results."

This statement was signed by Nancy Bray Boggs, Vice President, Human Resources & Corporate Communications. In response to inquiries from The Dark Report, Boggs provided a detailed statement just as this issue went to press. That statement will be printed in full in the next issue of The Dark Report.

Trouble In One Marriage

False positive results for Chlamydia caused major problems for one patient in her marriage. *6News* reporter Rafael Sanchez interviewed Tracey Sturm. "I assumed that my husband had cheated on me," said Sturm during an interview, which is available at *www.theindychannel.com/news/27441938/detail.html*. "I kicked him out of the house. He insisted he didn't do anything."

Mid America Clinical Labs Explained Source of Lab Test Errors and Corrections

IN ITS STATEMENT DATED APRIL 4, 2011, Mid America Clinical Laboratories (MACL) discussed its actions once it had detected errors in its Chlamydia testing program.

"MACL uses a very complex and sensitive process when testing for Chlamydia," wrote Nancy Bray Boggs, Vice President, Human Resources & Corporate Communications. "This molecular testing uses strand displacement amplification (SDA), which is FDA cleared. Small sequences of DNA unique to Chlamydia are located by molecular means within the gene sequences of the infectious organism within the patient sample and are replicated exponentially so they can be seen by the instrument, and therefore diagnosed as such. This SDA method is extremely sensitive and specific for the identification of Chlamydia.

"The amplicon (the amplified copies of the chlamydia DNA achieved through the SDA process) can escape into the testing environment resulting in cross-contamination of otherwise negative patient samples," the statement continued. "That is what happened in this case. When our negative quality control tested positive, we immediately stopped testing, notified physicians involved, notified the Indiana State Department of Health, and sent original, affected specimens to another laboratory for testing. As well, all subsequent test orders were sent out for testing.

"At the same time, because the source of contamination seemed to be within the instrument, we took all necessary steps to clean and replace parts in the instrument," the statement continued. "However, it was found that there was additional cross-contamination in the environment that resulted in additional cleaning followed by subsequent quality control checks. Testing resumed once that had been completed.

"A root cause analysis has been performed and we modified some processes to minimize this from happening in the future," concluded Bray Boggs in the statement.

A second test confirmed that Sturm did not have Chlamydia. Otherwise, she may have sought a divorce from her husband of 18 years, she told Sanchez.

The MACL statement disclosed that the error occurred because the eight samples were cross-contaminated as a result of the strand displacement amplification (SDA) method that the lab's analyzer uses when testing samples for Chlamydia.

➤MACL's Corrective Actions

Bray Boggs told *6News* that: 1) the lab was cleaned since the false positives were reported; 2) the parts of the machine that caused the contamination were replaced; and, 3) the equipment is now housed in a room in the laboratory where the air flow can be better contained.

In Sanchez' video report, the machine appears to be a **BD** Viper. As of press time, BD's public communications office had not returned calls from THE DARK REPORT requesting comments.

The publicity surrounding the public disclosure of erroneous laboratory test results reported to patients is a reminder to all pathologists and lab administrators that the quality bar is rising. Both physicians and patients expect near perfection from their lab testing providers.

After discovering it had reported false positive results for Chlamydia tests involving eight patients, Mid America Clinical Laboratories appears to have complied with federal and state lab regulations governing this type of incident. On the following pages, THE DARK REPORT offers some additional insights about how labs should respond to these types of events. **TDR**

Analysis of Lab Test Error Offers Lessons for Labs

Experts explain how systemic problems can lead to reporting false positive results

CEO SUMMARY: As happens now and again, a rather typical example of an error in lab testing has made the nightly news in Indianapolis because of one justifiably irate patient who got a false positive test report for an STD. One pathologist, asked by THE DARK REPORT to assess the public information about this episode for lessons to be learned, pointed out that there are at least four major systemic problems in today's lab testing environment that contribute to these episodes. But fixes to these systemic problems are not likely to happen soon.

EACH TIME A CLINICAL LABORATORY determines that it has reported inaccurate lab test results for one or more patients, it is required to take specific actions to correct the situation and minimize patient harm. It must also conduct a root cause analysis to determine the source of the error and fix those problems.

On April 4, 2011, **Mid America Clinical Laboratories** (MACL) in Indianapolis, Indiana, issued a public statement acknowledging that it had reported false positive results for Chlamydia tests. The statement then described how the laboratory had notified the physicians and patients involved. MACL offered free re-testing and other compensation for expenses incurred by patients as a result of the false positive tests.

MACL's statement also described certain of the findings of its root cause analysis, along with steps it was taking to correct the problem and prevent similar problems in the future. The lab test errors involved a molecular test for Chlamydia that is based on Strand Displacement Amplification (SDA), a methodology cleared for market by the FDA. Television news coverage of the incident showed a **BD** Viper instrument in the laboratory and stated that MACL had reported false positive results for Chlamydia on eight patients. *(See pages 9-10.)*

As this issue of THE DARK REPORT went to press, Mid America Clinical Laboratories provided a detailed statement about this matter in response to our requests for information. MACL's statement will be published in full in the May 23 issue of THE DARK REPORT.

Preventing Lab Errors

To provide other pathologists and lab administrators with useful insights about this laboratory error, THE DARK REPORT asked laboratory experts to review the first MACL public statement and the public news coverage of the episode. Their assessments brought out additional issues that were not recognized or discussed in MACL's statement about the findings of its root cause analysis.

In Canada, Michael A. Noble, M.D., FRCPC, has been a leader in developing

proficiency testing programs and helping laboratories improve quality. He is the Professor and Chair, Clinical Microbiology Proficiency Testing program and, Program Office for Laboratory Quality Management in the Department of Pathology and Laboratory Medicine, at the **University of British Columbia**, in Vancouver.

Noble went straight to the heart of the matter. He asserts that, involved in every case of laboratory error, there are systemic issues that often go unrecognized or unacknowledged. Noble thinks these systemic issues likely played some role in the false positive results acknowledged by MACL, but he wanted to emphasize that systemic problems in laboratory testing are an industrywide issue that doesn't get adequate attention.

Noble identified four specific ways that systemic problems can contribute to false positive test results and other types of laboratory errors.

➤Laboratory Equipment

"The first systemic problem that comes into play involves the limitations and failures of the equipment and diagnostic analyzers used in today's modern clinical laboratory," stated Noble. "Lab directors know that lab equipment fails.

"Yet this information is not normally disclosed to physicians or to patients," he observed, "despite the fact that such disclosure would be instructive for parties reviewing test results, particularly physicians and patients.

"Second, the errors at MACL likely could not have been prevented by accreditation or with proficiency testing," declared Noble. "The punitive nature of proficiency testing does little to encourage labs to identify some of the problems that lead to false positive results.

"Third, there are systemic problems in healthcare, in medical malpractice, and in the clinical practice of medicine by physicians that likely contributed to the error rate MACL experienced," added Noble. "The fourth systemic problem is in the lab itself, because, when errors occur, many laboratories do not respond quickly enough."

Noble provided details about each of these systemic problems that exist today in laboratory medicine. "In my view, the number one systemic problem involves the equipment used in laboratories today," he commented.

➤More Complexity In Labs

"As our laboratories continue to acquire and use more sophisticated diagnostic technologies and more automated testing, we add complexity," he explained. "The nature of automation is that it increases the likelihood that our labs will have accidents, errors, and slips that go by—often unnoticed until after the fact.

"We need to recognize that every piece of machinery will fail," declared Noble. "And they typically fail in a way that does not trigger an alarm. That is the norm.

"In Canada, pathologists have had problems with similar machines used by MACL for its molecular testing," he stated. "In these situations, it was determined that the problem was a carry over problem within the sample dilution system. Carry over and contamination problems within automated analyzers is a recurrent theme. This is one type of recurring lab problem that accreditation and proficiency testing won't stop.

"In addition, we know that the manufacturers of these analyzers can provide information on the false positive rate for each machine that they make," he added. "In fact, most analyzers tend to have a false positive rate of about 1 in 1,000; some are higher and some are lower. Knowing the false positive rate within a reasonable level of confidence would allow a pathologist to add that information to each report, thereby providing context for each result.

"But we don't do that," Nobel continued. "We say the result our lab is reporting was positive or negative as if we have

100% confidence, which we don't have. It's dishonest not to share that information with our physician clients and with patients. We assume that physicians and patients understand this point. But they don't."

Noble's second systemic problem involves the issues associated with accreditation and proficiency testing. "Reviewing the facts of the MACL case from the outside looking in, we don't know all the details about what happened," he said. "But my view is an error of this sort would not be prevented because of the lab's accreditation and proficiency testing activities.

"This should be troubling to all laboratory professionals," continued Noble. "The primary goals of accreditation and proficiency testing programs are to help laboratories drive out sources of errors and continually raise the accuracy and quality of their laboratory testing services.

"Yet, we can all recognize ways that these program requirements discourage full disclosure of problems," he said. "In this regard, accreditation and proficiency testing play a systemic role in contributing to errors and inaccuracies in laboratory test results.

Litigious Environment

"The third systemic issue involves the litigious environment that exists here in Canada and in the United States," he said. "One consequence of being litigious is that physicians do more testing than they would normally.

"Physicians practice defensive medicine because they don't want to be identified as having missed something by failing to test," he explained. "On the one hand, these litigious tendencies force overuse. But on the other hand, it also forces under-disclosure because the threat of litigation inhibits labs and manufacturers from admitting mistakes. The failure to admit mistakes creates additional problems because all labs lose the opportunity to learn from these mistakes.

Another Opinion About the Lab Error

UPON REVIEWING THE PUBLIC INFORMATION about the false positive results reported by Mid America Clinical Laboratories (MACL), one lab expert posed a basic question about how the test results were reviewed before they were released.

"The first flag for me that there would be a problem with this batch of tests is the number of positives that came up on this test run," stated an experienced medical technologist (MT) who has extensive experience as a Lean, Six Sigma, and process improvement consultant. "MACL stated that 'because the error was found quickly, it only affected 2% of the tests performed during this time period.'"

"I would want to know why the laboratory staff let all eight false positives go out along with the other positive Chlamydia test results reported that day," continued this expert. "Most labs wouldn't let that number of positives go out, because the history of sexually transmitted diseases is fairly steady. So if on one day, the lab had a larger than expected number of positives, it might be best to look for a reason before releasing all the positive test results."

"The overuse issue contributes to the systemic problem because you have large number of generally healthy people being tested on lab analyzers that were never designed for testing well people," Noble continued. "Assume we have a piece of equipment with (let's pick an arbitrary rate) a 1 in 1,000 chance of producing a false positive. If you test 1,000 patients each week, you have a probability of one person getting a false positive result every week.

"But then if you make it popular to do chlamydia testing and do one million patients per week, you will pick up 1,000 false positives every week," Noble said. "Now you have 1,000 wives accusing their husbands of infidelity, and of that num-

ber, you could have 50 divorces! In part, the problem is that the lab testing errors don't get picked up quickly enough. But the bigger problem is that most of those patients who were tested should not have been tested in the first place.

"But they get tested for two main reasons," he said. "First, clinicians are afraid they will be sued if they don't test. Second, it's a financial 'problem,' because many labs have invested huge amounts of money to install this expensive equipment. The only way to recoup the cost of those machines is to test hundreds of thousands of well people who end up with negative results. In this regard, we have set up a system of lab testing that is destined to bite us."

Noble then shifted to his fourth systemic issue, the slow reaction time of laboratories to problems in the process of lab testing. "This fourth systemic issue is that most labs don't have a way to pick up false positives quickly when they occur," he observed. "That means operations continue because most labs are blind to these problems.

"In the typical clinical lab, it is not until there are five, 10, 15, or 20 false positives that someone in the lab might say, 'Maybe we have a problem,'" Noble said. "Conversely, a laboratory with a good quality management system (QMS) tends to have a very active incident-reporting process in place. This helps the lab be much quicker at early detection of problems.

A Quality Lab Operation

"From what we know about MACL, there are indications that this is a quality lab," Noble continued. "The fact that they got to eight results and recognized that they should investigate is a good thing. They didn't wait until they got to 1,000 possibly inaccurate test results before they investigated.

"Still, the lab did report false positive results to those eight patients. This demonstrates a fact known by all pathologists and laboratory professionals: when the number is small, it is difficult to distinguish a positive result from a false positive result without re-testing," explained Noble.

THE DARK REPORT observes that there are useful lessons to be learned from this case. Dr. Noble's insights about the systemic issues that contribute to laboratory errors demonstrate how difficult it is for individual labs to eliminate all sources of errors.

TDR

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Questions About Proficiency Testing

COULD BETTER PROFICIENCY TESTING help medical laboratories prevent false positive test results? "Yes! Almost certainly!" asserts pathologist Michael A. Noble, M.D., who is active in laboratory proficiency testing programs at the University of British Columbia, in Vancouver, Canada.

"In North America, proficiency testing is required of clinical laboratories," stated Noble. "But what prevents proficiency testing from making a greater contribution to improved quality in laboratory testing is its punitive nature.

"There is a huge consequence if the lab gets something wrong and fails the proficiency test," he explained. "This gives the laboratory a strong incentive not to do proficiency testing in a straightforward manner, but to game the process as much as possible to get the correct result.

"If a lab can get the correct result by repeating the test, or by getting the correct result from someone else, then the lab will do so," continued Noble. "The consequences of failing the proficiency test are so high that no lab can afford to fail, so we miss the opportunity to identify problems and correct them—then share those findings with other laboratories so they can eliminate similar problems in their laboratories."

Office-Based Physicians Want In-Clinic Laboratories

Consultant says number of POLs is growing as doctors seek more revenue from ancillary services

CEO SUMMARY: Interest by office-based physicians in creating an in-clinic medical testing laboratory is on the increase. This has direct consequences for independent commercial labs, hospital lab outreach programs, and anatomic pathology groups, since office-based physicians are a primary source of lab test referrals. One consultant says that 60% to 70% of the volume of tests going out of many physicians' offices are routine tests that can be done in a physician office laboratory (POL).

THESE DAYS, GROWING NUMBERS of office-based physicians are taking steps to build and operate a clinical laboratory capable of moderately complex testing in their medical practice. That's the experience of a consultant who advises physicians on the set up and operation of in-clinic laboratories.

This trend has serious implications for the laboratory testing industry. It is the test referrals of office-based physicians that represent the largest competitive market segment for independent commercial lab companies, hospital laboratory outreach programs and anatomic pathology groups.

Thus, were large numbers of medical groups to establish an in-clinic medical laboratory capable of doing complex lab testing, this would reduce the volume of lab specimens these physicians refer to independent commercial laboratories.

In the next few years, a greater number of POLs (physician office laboratories) running complex testing could noticeably erode the current number of test referrals flowing from office-based physicians to their lab testing providers.

"In my consulting practice, I see two primary reasons why physicians decide to create an in-office laboratory," stated Tim Dumas, CLS, of Raleigh, North Carolina, who calls his POL consulting practice **Tim The Lab Guy** (*www.timthelabguy.com*). "First are the clinical benefits of having an in-office laboratory. Second are the financial benefits of offering this ancillary service.

Boosting Office Productivity

"Physicians who are savvy about management and workflow are quick to see that having an in-office laboratory can help them improve patient care while running a more productive office," noted Dumas. "When they can get chemistry and hematology tests within minutes—and not have to wait for their outside laboratory provider to deliver test reports the next morning—they have the information they need to treat the patient on the spot.

"I like to say that 'faster results gives faster treatment and faster recovery,'" commented Dumas. "That is a boost in the overall productivity of the medical practice. In turn, faster access to laboratory test

results has significant revenue benefits for physicians beyond the POL itself.

"The second major reason why physicians establish a POL is to create a source of ancillary revenue," stated Dumas. "Whether it's an outside commercial laboratory or the physician's in-house lab, someone is going to get paid for these tests. So these doctors ask themselves 'why shouldn't our medical practice get this revenue?'"

A Growing Opportunity

During the past 10 years, Dumas has grown his business from advising one physician office laboratory to working with about 45 POLs as a consultant and a clinical laboratory scientist (CLS).

"Because of declining reimbursement and pressure to improve measured improvements in patient health outcomes, physicians are waking up to the value that a POL can bring to their medical practice," stated Dumas. "These are the reasons why my POL consulting business has grown exponentially over the last five years. I'm adding about one to two POLs per month.

"Primary concerns my clients have are: 1) accuracy of test results; 2) compliance with CLIA, federal, and state regulations; and, 3) maintaining the profitability of their POL," observed Dumas.

"Because most of the laboratories perform only moderately complex testing, they are CLIA compliant and many are COLA registered," he explained. Dumas says that the increasing number of reliable, automated benchtop-sized analyzers is contributing to increased physician interest in establishing an in-office laboratory.

Capital Requirements

Start-up costs for a POL are reasonable. "A full package deal that includes hematology and chemistry analyzers and an LIS (laboratory information system) costs around $75,000," explained Dumas. "It takes about six months for a POL of average size to make back that investment."

Dumas has his clients working with an LIS called LabTrack. "This LIS communicates with all the lab test analyzers," he noted. "The LIS assigns a bar code, accepts orders from the EMR, and sends back notes and results to the EMR. A physician can install this robust IT solution for approximately $15,000.

"The economics of operating a POL are straightforward," continued Dumas. "Most physicians send out 100% of their lab tests. A full-year utilization report from their laboratory provider helps me determine the financial viability of their proposed POL.

"The largest volume of tests referred to outside lab providers are CBCs, chemistry profiles, and lipids," he stated. "These make up 60% to 70% of the volume of tests going out. If total testing volume for those physicians generates reimbursement of about $500,000 per year, the physicians might be able to keep $300,000 of that volume in-house and it will cost them about $75,000 up front to do that.

POL Generates Revenue

"When I ask, 'Are you interested?' they almost always say, 'Yes.' And why not?" Dumas asked. "Assume that POL start-up expenses are amortized over five years. The expenses for a lab tech, regulation fees, and reagents will be around $8,000 a month. Against those costs, a typical POL will generate about $20,000 a month in revenue.

"Physicians immediately recognize that this revenue can help them pay for staff, rent, and other operational expenses," observed Dumas. "However, there are physicians who see only the costs and don't look at the return on investment (ROI). They are the ones who pass on this opportunity. Those physicians who look at the ROI will often accept the financial risk of setting up a POL.

"Usually a single-provider practice can't afford to operate a POL," he stated. "The physician doesn't order enough laboratory tests to support the cost of an in-clinic laboratory.

"The economics of a POL become favor-

Simple, But Powerful Economics Support Operation of a Physician Office Laboratory

CERTAINLY THE ECONOMICS of a physician office laboratory (POL) can be compelling. But new pressures on physicians to handle more patients each day and improve patient health outcomes that are measured by Medicare and private payers are also reasons why a POL represents an attractive ancillary service for office-based physicians.

"Typically a physician and I will start with lab test volume and the financial analysis of a proposed POL," explained Tim Dumas, CLS, Founder of the POL consulting practice known as Tim The Lab Guy. "Then we will determine if rapid access to lab test results can help the operational and clinical performance of his or her medical practice.

"The questions are basic," he noted. "What tests do your patients need? How many of these tests do you order every month or every year? From those numbers, we calculate the potential revenue. If we ran the tests that most patients need every year, we could generate about $100,000 in revenue. Then we ask: What will it cost?

"The hematology analyzer costs about $15,000 and the chemistry machine about $30,000 to $40,000," continued Dumas. "We plug these numbers into a spreadsheet and estimate the start up costs and income for the proposed POL each month.

Five-Year Amortization

"The physician can amortize the cost of each analyzer over five years," he noted. "This allows him or her to see a very quick return on investment (ROI). Another big decision involves running complex testing in the POL. If the decision is yes, then the POL must meet stricter regulatory requirements.

Dumas says that each medical specialty will want to emphasize a different mix of on-site medical tests for their POL. "Let's say I set up a lab for an oncologist," he said. "The main tests oncologists run are CBCs, and, increasingly due to newer drugs, they need to monitor kidney function before administering chemotherapy.

"A CBC machine costs about $15,000, but almost every patient seen by an oncologist needs that test and it's best to get the test done in the doctor's office before administering chemotherapy," he explained. "With a POL, in as little as five minutes after the patient has given blood, the CBC test results are back in the chart ready for the physician to review. It costs the oncologist's POL about $1.00 to perform a single CBC test. Medicare reimbursement for that test is $10.54.

"Most oncology practices have three, four, or more physicians, meaning they need to do numerous CBCs every day," Dumas said. "And as the medication changes for a particular patient, the oncologists might want a calcium or a protein level. A patient's kidneys may need to be checked before prescribing certain new medications and that often involves a creatinine test and a magnesium level. These examples show how operation of an in-clinic laboratory contributes to significant improvements in patient care.

"Other physician specialties can also benefit from POLs," he continued. "This is true of any doctor checking cholesterol, diabetes, or thyroid problems, or any conditions for which the physician does not need to consult another specialist.

"Urgent care centers get great benefit from the POL," noted Dumas. "When a patient presents with a possible virus or bacterial infection, having the results within minutes of the CBC with white cell count and the differential becomes essential. It allows the physician to make an immediate decision on whether to prescribe an antibiotic. In cases where appendicitis is suspected, fast access to the CBC results run in the POL contributes to a rapid, accurate diagnosis. In turn, that allows the physician to act quickly to treat the patient."

able for groups that have three, four, or more physicians in the practice," said Dumas. "Specialities where the value of an in-clinic laboratory is highest include primary care, family medicine, pediatrics, internal medicine, oncology, and HIV clinics.

"These physicians want to run their own chemistry, blood, and lipid or cholesterol tests because having rapid access to these test results allows them to make faster diagnoses and start therapies quicker—often while the patient is still in the office.

Same List of Top 10 Tests

"The tests they want are the same top 10 tests that any doctor orders," added Dumas. "The list includes CBC, CMP, lipid panel, liver function, diabetes, glucose, and kidney function tests. The physicians need a basic chemistry profile and a basic blood count.

"Some offices do a high volume of thyroid tests," he recalled. "If the group has five doctors or more, we put in an analyzer that does PSA (prostate-specific antigen), TSH (thyroid-stimulating hormone), and free T4 (thyroid level) tests. There are tests doctors use when doing a full physical.

"For these physicians, we set up moderately complex analyzers that require an operator with a high school diploma to run," Dumas continued. "POLs could still use the services of pathologists. Every POL must have an approved lab and a medical director who oversees and reviews these lab testing activities."

Just as clinical laboratories and anatomic pathology groups have seen a steady decline in reimbursement for their most important CPT codes over the past 20 years, the same thing has happened to reimbursement for the most important CPT codes in every medical specialty. Like laboratories, physicians feel this financial pain.

"Many physicians recognize they make less today, in inflation-adjusted terms, than they did 20 years ago," concluded Dumas. "Faced with rising costs and the need to finance an EHR (electronic health record) system, it is no surprise that the financial and clinical benefits of a POL are more attractive today than in the past."

TDR

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—Joe Burns

Paperless POLs Interface with EMRs

"MANY PATHOLOGISTS AND CLINICAL LABORATORY MANAGERS are unaware of how automation and integrated informatics have changed the daily operation of a POL (physician office lab) doing moderately complex testing," said Tim Dumas, Founder of the POL consulting firm known as Tim The Lab Guy.

"*In vitro* diagnostics (IVD) manufacturers have automated almost everything," he observed. "These instrument systems are easily interfaced to a laboratory information system (LIS) and the LIS is interfaced to the new EMR systems."

"Most of my clients' POLs are paperless," continued Dumas. "This eliminates the transcription errors that often still occur in labs and pathology practices. Because the physicians are doing computer order entry, all information comes directly from the doctors and no staff member in the medical practice is writing paper orders.

"In these paperless environments, the doctor orders a lab test in the EMR," he said. "The EMR transmits the lab test order directly into the POL's LIS, where a bar coded label with the patient's name and the information is printed.

"The sample—with a label and bar code—goes onto the analyzer," stated Dumas. "The analyzer performs the tests ordered by the doctor, then electronically reports the results back to the LIS. A review of all the results is conducted, then the results are released into the patient's EMR record. In minutes, the lab test results are available to the physician who ordered the tests."

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Another laboratory information system (LIS) product has received certification as meeting stage 1 meaningful use (MU) measures. On March 31, **McKesson Corporation** announced that the **Drummond Group's** ONC-aTCB 2011-2012 (ATCB 2011/2012) certification as a compliant EHR module was given to the McKesson Horizon Lab LIS.

MORE ON: *Certification*

In a similar development, **Sunquest Information Systems** issued a press release on April 25, stating that its Physician Portal version 5.1 was certified as an EHR module that was compliant with the ONC-ATCB 2011/2012 criteria for meaningful use (MU). The certification came from the **Certification Commission for Health Information Technology** (CCHIT). Physician Portal version 5.1 is part of Sunquest's Outreach Advantage Suite, designed to support hospital laboratory outreach programs.

TRANSITIONS

• **Plus Diagnostics** of Union, New Jersey, appointed David Paluzzi as Chief Executive Officer (CEO). Paluzzi has served as President and COO at Plus Diagnostics since 2008. Paluzzi has held positions with **Quest Diagnostics Incorporated**, **US Labs**, **Ventana Medical Systems**, and **Abbott Laboratories**.

• Last month, **Orchard Software** of Carmel, Indiana, promoted Curt Johnson to Chief Operating Officer (COO). Johnson was formerly the Vice President of Sales and Marketing at Orchard.

• **Agendia, Inc.**, with U.S. offices in Irvine, California, recently installed a new management line-up. Its new Chief Operating Officer (COO) is David MacDonald, who has served at lab companies ranging from **AltheaDx** to **Nichols Institute Diagnostics**. Agendia's Executive Vice President of North American Sales is now Mark Willig, recently of **Thermo Fisher**. Serving as Vice President of Sales and Marketing is Doug Bradley, who came to Agendia from **Vertos Medical**.

• In March, Gregory Church was named Director of Marketing at **4medica**, headquartered in Culver City, California. He was formerly a Founder and Vice President at **InSync Marketing Group**.

That's all the insider intelligence for this report. Look for the next briefing on Monday, May 23, 2011.