Volume X, Number 16 Monday, December 1, 2003

• Exclusive Analysis! •

Changing Compliance Trends in the Lab Industry

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

ABNs, Client Billing, "Free Testing" & Medicare Rules

BY ANY MEASURE, ENFORCEMENT ACTIONS by the **Office of the Investigator General** (OIG) for Medicare fraud and abuse within the laboratory testing industry was a big story during the 1990s. I wonder if we might not be at a crossroads that could take our profession down a similar path in this decade.

There are interesting developments which lead me to this speculation. First, compared to the final years of the 1990s, there are a growing number of whispered complaints about the compliance practices of some laboratories competing for lab testing business from physicians' offices. The noise level from grumbling about different compliance policies is noticeably louder today than it was two or three years ago. That's a sign that something is changing across the laboratory services marketplace.

Second, there seems to be more examples where some laboratories are relatively lax about requiring ABNs (Advanced Beneficiary Notices) and back-charging client-bill accounts (whenever the client has failed to provide diagnostic codes and other information required to file a proper claim with Medicare). In the absence of more detailed guidance and enforcement action from federal healthcare regulators, labs willing to push these types of compliance boundaries are gaining competitive advantage over those laboratories which operate from more conservative policies of Medicare compliance.

Third, the willingness of certain laboratories to use the "free testing" strategy in more geographical locations and on a wider scale has the potential to trigger a host of negative financial consequences on the entire industry. At some point, it is likely that Medicare will notice and begin to factor the "free testing" characteristic into their reimbursement policies. In selected markets, there are signs that private payers have noticed and are using "free testing" examples to justify different reimbursement arrangements.

With federal healthcare regulators generally silent on a host of laboratory testing compliance issues, it is not surprising that a growing concern for laboratory directors and pathologists is uneven Medicare compliance practices. They are disturbed about how this puts them at a short-term competitive disadvantages. But they are also concerned that, if these practices continue to become more common, the sleeping regulatory giant may awake and slap the entire lab industry with onerous compliance requirements and possibly even penalties. TDR

"Free Testing" Strategy Stirs the Pot in Tenn.

Quest Diagnostics runs afoul of major payer as it seeks to build specimen volume

CEO SUMMARY: In Tennessee, the state's Medicaid HMO plan has been at odds with Quest Diagnostics Incorporated, which is using the "free testing" strategy to expand its share of the market. In recent months, TennCare Select has taken active steps to insure its physicians understand that Quest Diagnostics is not a contract provider for "included testing" and is only a provider for "excluded testing."

"FREE TESTING" IS STILL A STRATEGY used by some national laboratory companies. In recent months, its use in Tennessee has created a dust-up between **Quest Diagnostics Incorporated** and **Blue Cross/Blue Shield of Tennessee**'s (BCBS) TennCare Select program, the state's Medicaid HMO.

This dust-up between BCBS and Quest Diagnostics is a good example of the negative effects that result from use of the "free testing" strategy. It also illustrates why continued use of the "free testing" strategy by the nation's largest laboratory companies has the potential to bring negative financial consequences down on the entire laboratory testing industry.

To understand this threat posed by continued use of the "free testing" strategy, it is important that laboratory directors and pathologists know about several dimensions in this unfolding story. The first element involves Medicare compliance standards and when the use of "free testing" meets the requirements of a specific fraud alert published by the **Office of the Inspector General** (OIG) in December 1994.

Next, it is helpful to understand how Quest Diagnostics' use of the "free testing" strategy put it in conflict with the TennCare program. Quest Diagnostics is not a contract provider for TennCare Select's primary laboratory testing agreement. The dispute between these two companies provides a real-world

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.)

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).

example of why use of the "free testing" strategy does not always create a win-win outcome for either the clinical lab or the health insurance plan.

The third dimension involves short-term and long-term ramifications to the entire laboratory industry that result from continued use of the "free testing" strategy by the industry's largest companies. For lab executives and pathologists with long memories, it parallels the financial damage done throughout the 1990s as a consequence of the decision earlier in that decade by the public laboratory sector to bid for HMO contracts using marginal cost pricing.

Understanding The Strategy

First, an explanation of the "free testing" strategy. As used by national laboratory companies, it seems to be applied in two basic situations. In the first instance, if the lab company held a managed care contract and lost it during the rebidding process, it wants to protect its access to the non-contracted specimens from its client-physicians.

It will approach physicians with an offer to waive testing fees for that HMO's patients as a way to encourage the physician to continue sending his/her non-contract lab testing their way. Under this arrangement, the physician does not have to split specimens between one or more laboratories. Instead, the national laboratory will accept 100% of the physician's laboratory specimens, perform the requested tests, and report the results.

No Bill Sent by Nat'l Lab

But for patients covered by the contract which excludes the national laboratory, no bill will be sent to the health plan, the referring physician, or the patient. The lab company writes off this business as a way to retain access to non-contract specimens, including Medicare specimens.

This is the marketing strategy used by Quest Diagnostics in Detroit last year, after **Joint Venture Hospital Laboratories** (JVHL) wrested the last major exclusive HMO contract away from Quest Diagnostics in a competitive bidding process. JVHL is a regional laboratory network that represents hospital lab outreach programs.

The contract was with the **Health Alliance Plan** (HAP), involving about 125,000 lives in the HMO. On May 1, 2002 JVHL became the contract provider. Around that time, Quest Diagnostics sent its sales reps into physicians' offices that served HAP beneficiaries and began offering "free testing" for HAP HMO patients as a strategy to retain access to the non-HAP specimens (which include Medicare patients) and overcome JVHL's competitive advantage as the contract lab provider. THE DARK REPORT was first to cover this story and describe how all the public laboratory companies had formal corporate policies governing use of a "Waiver of Charges to Managed Care Patients" policy. *(See TDR, August 26, 2003.)*

Second Situation

The second situation where national lab companies use the "free testing" strategy is when they are in a regional market and they do not hold managed care contracts. Because they are not a contract provider, they find themselves at competitive disadvantage to the laboratories holding those contracts. In order to build specimen volume and market share, they approach physicians and offer to waive testing fees for patients covered by insurance plans to which they are not a contract lab services provider. One benefit from this arrangement is that the physician will not have to split specimens between one or more laboratories.

This is the situation in Tennessee. For several years, **Lab*One*, Inc.** of

Tennessee Medicaid HMO Doesn't Like "Free Testing" Strategy Used by National Lab

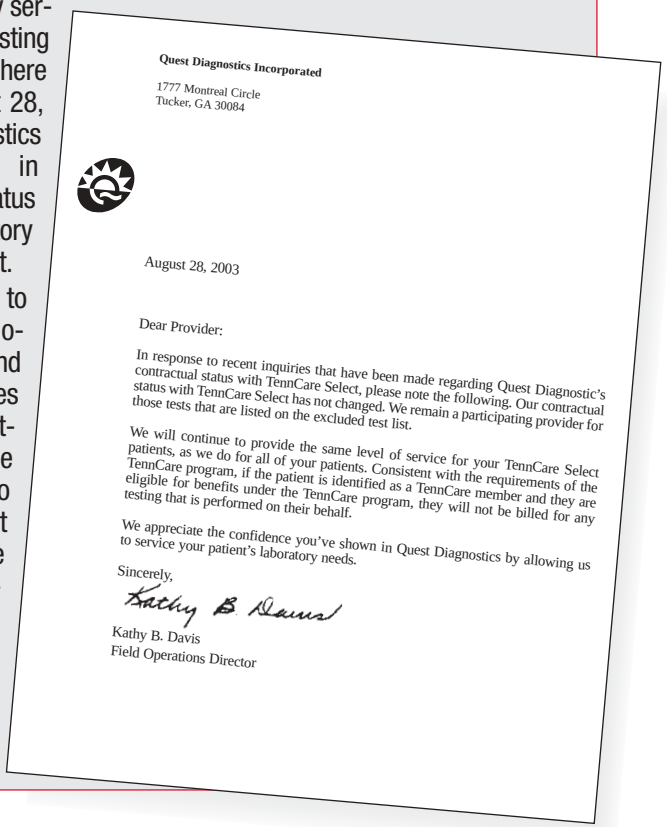
Who Is TennCare Select's Provider for All Lab Services?

TENNESSEE PROVIDES A FASCINATING LOOK at how use of the "Waiver of Charges for Managed Care Patients" strategy can frustrate the efforts of a major insurance plan to develop its network of contracted providers, including laboratory testing services.

For several years, Lab*One*, Inc. of Lenexa, Kansas has been the exclusive provider of laboratory testing for Blue Cross Blue Shield of Tennessee, Inc.'s statewide Medicaid managed care plan, called TennCare Select. As part of its sales and marketing campaign in Tennessee, Quest Diagnostics Incorporated has been willing to offer "free testing" for the patients of certain physicians in situations that Quest Diagnostics determines meets the requirements of the OIG's December 1994 fraud alert.

Apparently enough physicians got the impression that Quest Diagnostics was a contract provider for *all* laboratory testing, not just the menu of "excluded" tests that any laboratory can provide for TennCare Select Patients. To clarify this situation, in August 2003, Blue Cross Blue Shield of Tennessee sent a letter to all physicians noting that that nothing had changed; i.e., that Quest Diagnostics "is only contracted to provide those laboratory services identified by the existing exclusion list." Presented here is the letter, dated August 28, 2003, that Quest Diagnostics sent to physicians in Tennessee to clarify its status as a provider of laboratory testing for TennCare Select.

Of particular interest to lab directors and pathologists seeking to understand how competing laboratories use the "free testing" strategy is the language at the end of paragraph two which states "if the patient is identified as a TennCare member and they are eligible for benefits under the TennCare program, they will not be billed for any testing that is performed on their behalf."



Quest Diagnostics Incorporated

1777 Montreal Circle
Tucker, GA 30084

August 28, 2003

Dear Provider:

In response to recent inquiries that have been made regarding Quest Diagnostic's contractual status with TennCare Select, please note the following. Our contractual status with TennCare Select has not changed. We remain a participating provider for those tests that are listed on the excluded test list.

We will continue to provide the same level of service for your TennCare Select patients, as we do for all of your patients. Consistent with the requirements of the TennCare program, if the patient is identified as a TennCare member and they are eligible for benefits under the TennCare program, they will not be billed for any testing that is performed on their behalf.

We appreciate the confidence you've shown in Quest Diagnostics by allowing us to service your patient's laboratory needs.

Sincerely,

Kathy B. Davis

Kathy B. Davis
Field Operations Director

Lenexa, Kansas has held the exclusive lab testing contract for TennCare Select, the state's Medicaid managed care plan. Tennessee is a state where Quest Diagnostics currently has a relatively small market share. As it began to beef up sales and marketing efforts in Tennessee in recent years, it found that Lab*One* enjoyed significant competitive advantage because of its lab testing contract with TennCare Select. One reason was because of the relatively high proportion of Medicaid patients in Tennessee.

"Free Testing" Offered

To overcome Lab*One*'s advantage with its exclusive TennCare contract, sales reps from Quest Diagnostics began to offer "free testing" arrangements to physicians in Tennessee. The structure of these arrangements is designed to meet the requirements of the OIG's fraud alert of December 1994. That fraud alert described how and when a provider could "waive charges" for the proportion of a physicians' referral work that was covered by a managed care contract that excluded the provider, while continuing to accept and charge for all the other patients referred by the physician. *(See page 7-11 for a more complete explanation.)*

In Tennessee, it appears that Quest Diagnostics' use of the "free testing" strategy attracted enough physicians to create problems for Tenncare Select. The problems go beyond "leakage." As most lab managers know, when an exclusive lab testing contract exists between an insurance plan and a laboratory, any specimens tested by a non-contract laboratory have "leaked" out of the primary contract. Among other consequences, it means the health plan will pay a higher-than-contracted rate to the non-contract lab, which raises the health plan's budgeted expenses for laboratory testing services.

For TennCare Select, there were several unwanted consequences from the "free testing" strategy implemented by Quest Diagnostics to physicians in Tennessee. Because Quest Diagnostics waives charges for TennCare patients, TennCare did not get bills from Quest Diagnostics. But TennCare also does not get accurate utilization data on those patients and does not get lab test data for tests performed under the "free testing" arrangements that the lab has with client-physicians. This negatively impacts the ability of TennCare to compile complete and accurate HEDIS reports, to monitor utilization, and to measure outcomes.

Over time, Quest Diagnostic's marketing efforts apparently caused a growing number of physicians to switch their laboratory testing business to Quest, including the TennCare Select specimens. Eventually TennCare noticed this pattern and the diminished number of lab tests for beneficiaries enrolled in this program, along with the impact it had on accurate and complete reporting for HEDIS, utilization, and outcomes assessment.

TennCare Select Reacts

In August, TennCare Select sent a letter to physicians specifically stating that Quest Diagnostics was not a "participating provider in TennCare Select for all laboratory testing services." The letter further stated that it had requested that Quest Diagnostics specifically release a "written notice of clarification to providers that their [contract] relationship with Blue Cross/Blue Shield of Tennessee, Inc. had not changed. Providers should be informed that Quest Diagnostics is only contracted to provide those laboratory services identified by the existing exclusion list."

To respond to TennCare's request to clarify its contract status with the

TennCare lab testing contract, Quest Diagnostics sent a letter to physicians in Tennessee, dated August 28, 2003. The letter is reproduced on the previous page. In it, Quest Diagnostics describes its current contractual relationship with TennCare Select.

Reaction By Payers

This running disagreement between Quest Diagnostics and TennCare Select highlights a fascinating dimension about the use of "Waiver of Charges to Managed Care Patients" strategy by laboratories to work around the fact that they do not hold a contract with key managed care plans. As demonstrated by TennCare's public steps to insure that its network physicians know which laboratory holds the contract for "included testing," payers can view the "free testing" strategy as detrimental to the interests of its beneficiaries and the network of providers it has developed.

This may be counter-intuitive, since many would expect managed care plans to consider "free testing" as something that helps lower the overall cost of its healthcare services. However, there are powerful reasons why this is not true. Clients and regular readers of THE DARK REPORT know that reducing medical errors and improving the quality of healthcare services have become major goals within the American healthcare system.

Emphasis on Outcomes

Pressure on providers and insurers to demonstrate the quality of their service and publish outcomes is shifting emphasis away from utilization control (a primary objective of the closed-panel HMOs introduced during the 1990s). Now the emphasis is on measuring outcomes and collecting accurate information to demonstrate that outcomes and patient safety in an insurer's network are improving over time.

To accomplish both goals, health plans must collect complete and accurate data. This goes beyond simple utilization data. Payers want to see clinical data, including lab test results, and use this data to measure outcomes. If "free testing" has been done by laboratories outside the health plans contracted provider network, the long-term effects of losing this information outweigh the short term benefits of not having to reimburse for those tests.

In the last 15 months, THE DARK REPORT has briefed its clients on two examples where major regional health plans (in Michigan and Tennessee) have publicly declared their objections to an out-of-network laboratory using the "free testing strategy." Both examples demonstrate that there are more negative risks to this marketing strategy than the obvious exposure to potential allegations of Medicare fraud and abuse if the strategy is implemented inappropriately.

Now A Hot-Button Issue

Uneven compliance within the laboratory services industry has become both an emotional and financial issue with growing numbers of laboratory administrators and pathologists. In stories which follow, THE DARK REPORT will provide more details on compliance issues. One story will reproduce the OIG's December 1994 fraud alert and describe how some public laboratories have established corporate policies to utilize this fraud alert as a sales tool. This will be followed by a legal analysis of compliance issues triggered by the "free testing" strategy.

Building from this information, THE DARK REPORT will offer predictions about how and why the "free testing" strategy may lead the laboratory industry into another cycle of financial cutbacks reminiscent of capitated contracts and full risk agreements offered by laboratories in the 1990s. TDR

Contact Robert Michel at 512-264-7103.

"Waiver of Charges": What Makes It Work

December 1994 OIG fraud alert forms basis of this particular lab marketing strategy

CEO SUMMARY: Little-used in the 1990s, when laboratory test ordering and billing practices were under intense scrutiny by federal regulators, the strategy of "free testing" is popping up in more regions around the country. To comply with compliance guidelines, labs using this strategy generally ask the physician to sign contracts representing and warranting that circumstances of the arrangement meet the guidelines published in the OIG fraud alert.

When the **Office of the Investigator General** (OIG) first published the fraud alert addressing "Waiver of Charges to Managed Care Patients," it was not a good time for commercial laboratory companies.

The month was December 1994 and most of the nation's public laboratory companies were under federal subpoena to deliver records pertaining to billing and reimbursement practices involving Medicare and Medicaid patients. The federal government's investigation generated plenty of fines. Those laboratories which settled allegations of Medicare fraud and abuse entered into compliance agreements with federal prosecutors that gave the government the right, for up to five years, to come in and inspect company records if further infractions were suspected.

Not surprisingly, for the balance of the decade, executives at public laboratory companies decided that offering "free testing" to physicians in situations that met the criteria of the 1994 fraud alert was not a good idea, considering their immediate experiences with federal investigators.

However, the OIG's fraud alert did not go unnoticed. Nearly every public laboratory company conducted legal due diligence into this opportunity. Most developed formal corporate policies for its use in the marketplace, along with contracts to be signed when establishing "free testing" arrangements with physician-clients.

More Use Of The Strategy

In recent years, public laboratory companies and some regional laboratories have begun to use the "free testing" strategy more aggressively in situations where they do not hold contracts with specific payers to provide lab services.

As use of the "free testing" strategy increased, many hospital laboratory outreach programs had their health system legal teams review the 1994 OIG fraud alert. However, the reaction of most hospital and health system lawyers to this marketing concept was negative. Permission for the lab outreach pro-

OIG Defines "Waiver of Charges" Criteria

HERE IS THE EXACT LANGUAGE from the December 19, 1994 OIG fraud alert that addresses the subject of "Waiver of Charges to Managed Care Patients."

[Federal Register: December 19, 1994]
DEPARTMENT OF HEALTH
AND HUMAN SERVICES

Publication of OIG Special Fraud Alerts

AGENCY: Office of Inspector General, HHS.

Waiver of Charges To Managed Care Patients

Managed care plans may require a physician or other health care provider to use only the laboratory with which the plan has negotiated a fee schedule. In such situations, the plan usually will refuse to pay claims submitted by other laboratories. The provider, however, may use a different laboratory and may wish to continue to use that laboratory for non-managed care patients. In order to retain the provider as a client, the laboratory that does not have the managed care contract may agree to perform the managed care work free of charge. The status of such agreements under the anti-kickback statute depends in part on the nature of the contractual relationship between the managed care plan and its providers. Under the terms of many managed care contracts, a provider receives a bonus or other payment if utilization of ancillary services, such as laboratory testing, is kept below a particular level. Other managed care plans impose financial penalties if the provider's utilization of services exceeds pre-established levels. When the laboratory agrees to write off charges for the physician's managed care work, the physician may realize a financial benefit from the managed care plan created by the appearance that utilization of tests has been reduced.

In cases where the provision of free services results in a benefit to the provider, the anti-kickback statute is implicated. If offered or accepted in return for the referral of Medicare or State health care plan business, both the laboratory and the physician may be violating the anti-kickback statute. There is no statutory exception or "safe harbor" to immunize any party to such a practice because the Federal programs do not realize the benefit of these "free" services. See 42 CFR 1001.952(h)(3)(iii).

grams to deploy "free testing" to local physicians was seldom granted.

That is why there is an interesting dichotomy in today's laboratory marketplace. It is generally public lab companies which use the "free testing" strategy. In contrast, only a tiny number of hospital laboratory outreach programs are known to use it.

Besides the reluctance of their legal counsels to endorse use of "free testing" as a way to protect market share and expand lab test volume, most hospital laboratories cannot afford the cost of giving "free testing" to physician-clients. Many hospital laboratory administrators are also quick to point out that giving away testing for free to one managed care program is not a healthy business practice over the long term. Other payers in the region are sure to notice and use "free testing" examples to further drive down the reimbursement they offer for laboratory testing.

In the sidebar above, THE DARK REPORT has provided the exact language of the OIG's December 19, 1994 fraud alert pertaining to "Waiver of Charges to Managed Care Patients." The full fraud alert, which contains guidelines on other

(Story continues on page 11)

Forms Used to Establish "Free Testing" Arrangements Between Physicians and Labs

OUT OF NETWORK
LABORATORY SERVICES AGREEMENT

AGREEMENT MADE THIS _____ day of _____, 2002 by and between insert client name here ("CLIENT") and Laboratory Corporation of America ("LABORATORY").

WHEREAS, CLIENT desires that LABORATORY provide it and its affiliated physicians ("Physicians"), if any, with reference clinical laboratory testing services for its patients; and

WHEREAS, certain of CLIENT's and Physicians' patients are members of the following managed care plans(s): Insert Plan Name here (together hereinafter referred to as the "Plan"); and

WHEREAS, the Plan has an exclusive agreement with other laboratories to provide its patient members with reference clinical laboratory testing services and therefore, LABORATORY cannot be compensated by the Plan as a network provider or out-of-network provider;

IT IS THEREFORE AGREED AS FOLLOWS:

1. TESTING SERVICES
Based on the representations of CLIENT contained herein, LABORATORY agrees to provide CLIENT and its Physicians with reference clinical laboratory testing services for the Plan patient members at no charge to the Plan, the patient member, the CLIENT and its Physicians. Such services shall be limited to LABORATORY's routine and non-esoteric testing services which can be performed at one of LABORATORY's local facilities, as may be modified from time to time by LABORATORY, and such additional services as the parties may agree.

2. REPRESENTATIONS OF CLIENT
In order for LABORATORY to provide those services set forth in Section 1 of this Agreement, CLIENT, on behalf of itself and its Physicians, hereby represents and warrants:

A. LABORATORY's provision of its services to the Plan's members at no charge does not violate or breach any agreement that the Plan may have with CLIENT or its Physicians;

B. LABORATORY's provision of its services to the Plan's members at no charge does not result in any direct or indirect financial or other benefit to CLIENT or its Physicians whatsoever, including, but not limited to, any withhold pool or the receipt of any bonus or remuneration or the avoidance of a n y penalty based upon CLIENT's utilization of laboratory services; and

C. CLIENT's agreement with the Plan does not require CLIENT to perform or provide at its own expense any laboratory services for the Plan members nor does any compensation or payment to CLIENT from the Plan include any amount as reimbursement for laboratory services.

CLIENT further acknowledges and agrees that its representations and warranties shall continue throughout the term of this Agreement and CLIENT affirmatively agrees to notify LABORATORY immediately in the event there is any change in its representations and warranties herein. CLIENT agrees that LABORATORY may perform random audits in connection with this Agreement and the representations and warranties hereunder for the purpose of ensuring compliance with this Agreement and applicable laws, regulations and LABORATORY policies. Attached hereto as Exhibit A is a list of the Physicians affiliated with CLIENT who may participate in this Agreement. CLIENT shall obtain each Physician's signature on Exhibit A to ensure compliance with this Agreement. CLIENT shall immediately notify LABORATORY of any addition to or deletion from Exhibit A. If there is an addition to Exhibit A, CLIENT shall promptly obtain such Physician's signature on Exhibit A to ensure compliance with this Agreement.

WARRANTY
CLIENT WARRANTS TO LABORATORY THAT NEITHER CLIENT NOR ANY OF ITS PHYSICIANS, EMPLOYEES OR OWNERS HAVE BEEN DEBARRED, SUSPENDED, DECLARED INELIGIBLE, OR EXCLUDED FROM MEDICARE/MEDICAID OR ANY OTHER GOVERNMENTAL HEALTHCARE PROGRAM. LABORATORY WARRANTS TO CLIENT THAT ALL SERVICES PROVIDED HEREUNDER SHALL BE PERFORMED IN ACCORDANCE WITH ESTABLISHED AND RECOGNIZED CLINICAL LABORATORY TESTING PROCEDURES AND WITH REASONABLE CARE IN ACCORDANCE WITH APPLICABLE FEDERAL, STATE, AND LOCAL LAWS. NO OTHER WARRANTIES ARE MADE BY LABORATORY. THE LIABILITY AND OBLIGATIONS OF LABORATORY, AND THE REMEDIES OF CLIENT, UNDER OR IN CONNECTION WITH THIS AGREEMENT SHALL BE LIMITED TO REPEATING SUCH SERVICES PERFORMED; PROVIDED, HOWEVER, SUCH FAILURE OR NEGLIGENCE IS REPORTED IN WRITING TO LABORATORY WITHIN 30 DAYS AFTER THE DISCOVERY THEREOF, BUT IN NO EVENT LATER THAN ONE YEAR FROM THE PERFORMANCE OF SUCH SERVICES BY LABORATORY. IN NO EVENT SHALL LABORATORY BE RESPONSIBLE FOR ANY PUNITIVE DAMAGES OR ANY DIRECT, INDIRECT, CONSEQUENTIAL, INCIDENTAL, OR SPECIAL DAMAGES (INCLUDING LOST PROFITS OR REVENUE) OF CLIENT OR OF ANY THIRD PARTY. THE PARTIES ACKNOWLEDGE THAT THE SERVICES TO BE PROVIDED BY LABORATORY HEREUNDER COULD NOT BE MADE AVAILABLE UNDER THE TERMS PROVIDED HEREIN IF LABORATORY IS REQUIRED TO PROVIDE ANY REPRESENTATIONS, WARRANTIES OR GUARANTEES IN ADDITION TO, OR IN LIEU OF, THOSE EXPRESSLY SET FORTH IN THIS AGREEMENT.

HOLD HARMLESS/INDEMNITY
CLIENT acknowledges that any breach of its representations or warranties herein, whether knowingly or negligently caused, would create a situation in which CLIENT is being compensated for services performed by LABORATORY and for which LABORATORY should be compensated. Therefore, CLIENT agrees that in addition to other remedies, LABORATORY shall be entitled to any and all such compensation or other remuneration, plus interest, which CLIENT receives as a result of any breach of this Agreement or any representation or warranty herein. CLIENT further agrees to defend, indemnify, and hold LABORATORY, its subsidiaries, affiliated and related companies, directors, officers, employees, and agents, wholly harmless from and against all third party claims, losses, lawsuits, settlements, demands, causes, judgments, expenses, and costs (including reasonable attorney fees) due to a misrepresentation contained herein, or a breach of this Agreement by CLIENT or arising under or in connection with this Agreement.

TERM AND TERMINATION
LABORATORY's testing services shall be available hereunder for a period of one year commencing upon acceptance by LABORATORY, and continuing thereafter unless terminated by notice of either party to the other. This Agreement may be terminated by either party, with or without cause, at any time, by giving the other party written notice at least five (5) days prior to the effective date of termination.

CHANGE IN LAW OR REGULATION
The terms of this Agreement are intended to be in compliance with all federal, state and local statutes, regulations and ordinances applicable on the date the Agreement takes effect. Should legal counsel for either party reasonably conclude that any portion of this Agreement is or may be in violation of such requirements, or subsequent enactments by federal, state or local authorities, or if any such change or proposed change would materially alter the amount or method of compensating LABORATORY for testing performed for CLIENT or for any other party under this or any other Agreement, or would materially increase the cost of LABORATORY's performance hereunder, this Agreement shall terminate immediately upon giving the other party prior written notice thereof, unless the parties agree to such modifications of the Agreement as may be necessary to establish compliance with such authorities or to reflect such change in compensation or cost.

NOTICES
Any notice required or desired to be given pursuant to this Agreement shall be in writing and shall be given by certified mail or registered mail as follows:

PHYSICIAN ACKNOWLEDGEMENT OF NON-INTEREST

y name is _____. I am one of Quest Diagnostics' stomers. I affirm and warrant to Quest Diagnostics Incorporated that the following is true the best of my knowledge as of this date: _____.

I understand that this acknowledgement is a prerequisite to Quest Diagnostics waiving charges to _____
(name of managed care plan(s)
(the "Plan") for laboratory services [and/or specimen collections] performed for my patients who are enrolled in the Plan.

Neither I nor any member of my immediate family has or anticipates having any indirect or indirect ownership or investment interest in the Plan. For the purposes of this acknowledgement, I understand that "ownership or investment interest: means an interest in any form, whether established through equity, debt, or other means. I also understand that the term "immediate family" is broadly defined and includes: spouses, parents (natural, adoptive, and step-parents); children (natural, adoptive, and step-children; brothers and sisters (natural, adoptive, and step-brothers and step-sisters; grandparents (and their spouses); grandchildren (and their spouses), fathers-in-law; mothers-in-law; sons-in-law; daughters-in-law; brothers-in-law; and sisters-in-law.

I receive no compensation, remuneration, or benefit, either directly or indireclty, from the Plan, through risk sharing or otherwise, as a result of Quest Diagnostics waving charges to the Plan for laboratory services performed for Plan members [and/or specimen collections for Plan members whose testing is performed at the provider laboratory].

Beneficiaries under the Plan are not required pursuant to their membership agreement to pay any co-insurance, co-payment, or deductible with respect to any laboratory services performed by Plan providers.

I understand that the waiver of charges may be revoked at any time without notice. I further understand that the waiver will be revoked if Quest Diagnostics successfully enters into a provider relationship with the Plan.

I agree to inform Quest Diagnostics promptly if at any time in the future any of the above facts are no longer true.

te: _____

_____/_____
Physician's Signature UPIN Number

_____
Printed Name of Physician

Above are samples of contracts which the two national laboratories ask physicians to sign when establishing a "free testing" relationship designed to meet the criteria established in the OIG's December 1994 "Waiver of Charges to Managed Care Patients" fraud alert. The essential language in both documents is very similar, since the laboratories want the physician to represent and warrant that the OIG's criteria have been meet—and if there are changes to those criteria, like remuneration and financial benefit, the physician will immediately notify the laboratory of those changes. One interesting point is the title of these contracts. One is called "Out Of Network Laboratory Services Agreement." The other is titled "Physician Acknowledgement of Non-Interest." DIANON Systems, Inc. had its own version of this contract, which was titled "Physician Certification."

(Continued from page 8)

lab compliance issues, can be found at *www.oig.hhs.gov.*

When laboratories establish a business relationship with physicians that includes "free testing" and meets the criteria detailed in the OIG's fraud alert, the common procedure is to have the physician sign a contract acknowledging specific facts of the arrangement.

Similar Language In Forms

Examples of contracts used in the past by the Two Blood Brothers are shown on the proceeding pages. It is no surprise that each example contains language that is quite similar. Both laboratory companies want the physician to represent and warrant that the business arrangement meets the OIG's criteria for "Waiver of Charges to Managed Care Patients."

In particular, these contracts require the physician to warrant that he or she receives no financial benefit nor any form of remuneration from the managed care plan whose patients will receive "free testing" from the laboratory. Further, the physician warrants that he/she will notify the laboratory, if at any time, any representation made in the agreement changes.

Docs Have Responsibility

"From one compliance perspective, the laboratories have placed a significant legal burden on the physician," observed Jane Pine Wood, Attorney and Partner at **McDonald Hopkins**, based in Cleveland, Ohio. "It is the physician's representations and warrants that are used to document that the criteria set out in the OIG's "Waiver of Charges to Managed Care Patients" fraud alert have been met. It is also now the legal responsibility of the physician to notify the laboratory if there is a change in any of the representations and warrants involving financial benefit and remuneration change.

"In our healthcare practice, we have had physicians come to us with these types of contracts," she continued. "As we review the representations and warranties they are being asked to make, along with the potential legal consequences, many are surprised at how much responsibility they will assume in validating the circumstances required for the laboratory's "free testing" arrangement to meet the OIG's fraud and abuse criteria."

There is some irony in this situation. It is the laboratory which has initiated this arrangement. It will trade "free testing" for patients enrolled in a managed care plan as a way to get the physician to agree to refer his/her remaining lab specimens.

Potential Legal Exposure

Yet, in signing the laboratory's contract, the physician is making specific representations and warranties. If a subsequent OIG investigation was to determine that these were untrue from the start of the business relationship, or that the physician failed to notify the laboratory that some aspect of financial benefit or remuneration changed, that physician could face allegations of Medicare fraud and abuse.

Despite these facts, there is ample evidence in the marketplace that physicians are willing to sign these agreements and cooperate with "free testing" arrangements. That is one reason why Tennessee's Medicaid managed care plan, TennCare Select has taken steps to remind physicians about which laboratory is the contracted provider for "included testing services." If physicians continue to accept these arrangements, and if the OIG finds no compliance violations in their use, then the lab industry may see growing use of the "free testing" strategy. TDR

Contact Jane Pine Wood at 508-385-5227.

Lab Marketing Strategy Triggers Legal Concerns

TennCare's displeasure with this lab marketing gambit shows one risk

CEO SUMMARY: *That famous phrase "everyone wants something for nothing" does not describe TennCare Select's reaction to the "free testing" that Quest Diagnostics is performing for its beneficiaries. TennCare provides a real-world example of how this strategy can put a laboratory at odds with an important payer in a region. An experienced healthcare attorney assesses other legal risks from the"free testing strategy."*

BECAUSE CERTAIN ASPECTS of the "spat" between **Quest Diagnostics Incorporated** and **Blue Cross/Blue Shield of Tennessee**'s (BCBS) TennCare Select program have become public, it provides a rare opportunity to evaluate the impact of the "free testing strategy" in the laboratory testing marketplace.

One attorney familiar with the **Office of Investigator General's** (OIG) "Waiver of Charges to Managed Care Patients" fraud alert is Jane Pine Wood, a Partner at **McDonald Hopkins**, based in Cleveland, Ohio. Wood's law firm maintains a national healthcare practice that includes clinical laboratory and anatomic pathology clients, as well as physician group practices. Wood has researched this topic to provide legal advice to a range of healthcare clients who represent both sides of such arrangements.

"Use of the 'free testing' strategy can potentially violate existing laws in several ways," stated Wood. "The OIG's December 1994 fraud alert establishes specific circumstances which must be met to avoid violating Medicare fraud and abuse statutes. However, the criteria lacks the type of detail needed to create an objective and clearcut test that a lab can use to gauge individual situations.

Subjective Interpretation

"That subjectivity of interpretation is what opens the door for laboratories and providers willing to take a very loose compliance position," she added. "It allows them to aggressively pursue business practices in the competitive marketplace that puts laboratories operating from a more conservative compliance policy at a competitive disadvantage.

"I see this effect of the 'free testing' policy in my legal practice. I hear from my laboratory and pathology clients regularly on this and other compliance issues, including client billing arrangements and ABNs (Advance Beneficiary Notices). They say 'if I follow Medicare compliance policies in a strict

fashion, my lab finds itself at a significant competitive disadvantage!' I hear this theme repeatedly," observed Wood. "What my lab and pathology clients want is simply a level playing field. Because of uneven compliance practices, it doesn't exist."

Wood notes that inappropriate use of the "Waiver of Charges to Managed Care Patients" strategy can create legal exposure for a laboratory in several ways. "First, criteria in the December 1994 OIG fraud alert states only that neither the referring physician nor the patient can receive remuneration as a result of this arrangement," she said.

Compliance Checks

"This establishes one obvious compliance test to use in evaluating individual situations," continued Wood. "That is to look at whether the physician and/or the patient receives remuneration because the test that was performed was never billed to the payer, the patient, or the physician," stated Wood. "But remember that CMS and the OIG have not defined remuneration in specific ways that allow laboratories to create a more complete and objective compliance test.

Gauging Remuneration

"Obviously any financial reward paid to the physician for reduced utilization is covered by this fraud alert. Similarly, a co-pay, deductible, or out-of-pocket charge required of the patient that is waived by the laboratory is remuneration covered by the fraud alert," she noted. "But what about other forms of remuneration? Is there remuneration because the physician's office does not have to split samples? If the lab waiving charges has an agreement to maintain a phlebotomist in the office, but only so long as it gets all that physician's lab testing referrals, can that be categorized as remuneration?

"Arguments can be made that these, and similar items, are forms of remuneration that the OIG wants considered with its fraud alert criteria," added Wood. "After all, they do represent economic value to the referring physician."

"To date, there has been no specific guidance by either CMS or the OIG regarding this point," noted Wood. "Nor has there been an enforcement action that has come to public attention. Without that guidance, there are laboratories in the marketplace which stretch the intent of this particular fraud alert and gain competitive advantage over those labs which follow a conservative compliance policy."

Wood then listed other legal issues which can come into play when a laboratory uses the "free testing" strategy, including: 1) anti-trust violations, 2) anti-discrimination language in managed care contracts between the laboratory and payers; and 3) most-favored nations (MFN) clauses in managed care contracts.

"Arguments can be made that these...are forms of remuneration that the OIG wants considered with its fraud alert criteria," added Wood.

"Anti-trust violations can come into play," stated Wood. "As an example, most-favored nation clauses can become expensive to the lab doing 'free testing'," she continued. "If, for example, a payer like Aetna sees a laboratory doing free testing for Blue Cross patients, it certainly has the right to demand comparable pricing—free testing in this case—for its patients served by that laboratory."

In the case of Quest Diagnostics and its use of "free testing" for patients

covered by TennCare Select, Wood noted that the legal issues can become more complex. "For example, before entering an agreement to allow Quest Diagnostics to test and not bill for TennCare Select patients, do both Quest Diagnostics and the physician review his/her TennCare contract to identify possible areas of remuneration that would cause that relationship to violate the criteria set forth by the OIG fraud alert?" asked Wood.

"This lack of effective enforcement or compliance guidance is what causes many of our laboratory and pathology clients to tell me 'we just want a level playing field."

"In our healthcare practice at McDonald Hopkins, we often see physician-provider contracts with remuneration clauses that would cause a compliance concern if that physician entered into a "free testing' agreement with a laboratory."

Wood also had some observations about the language in the August 28, 2003 letter Quest Diagnostics sent to Tennessee physicians to clarify its status as a laboratory provider for the TennCare Select program. "As I understand the situation, TennCare was asking Quest Diagnostics to be clear with physicians about its status as a contract provider for "included testing" and "excluded testing." *(The full text of the letter appears on page 3.)*

"A careful reading of this letter indicates that nothing stated was false. But was it misleading? Some would argue that it is, particularly because there is no specific statement that it—Quest Diagnostics Incorporated—is a non-provider for 'included testing'," observed Wood.

"It is situations similar to these that strike to the heart of the 'uneven' compliance problem that exists within the laboratory industry. If a lab company wants to be honest and forthright, their public and private communications are invariably clear and transparent.

"That is not the case when a lab company wants to push the compliance boundary" she added. "In our law practice, clients bring us correspondence and written materials distributed by competitors with aggressive compliance policies. In such situations, these materials use misrepresentation and carefully-crafted ambiguity as one way to push the limits of compliance. That philosophy permeates their documentation, marketing materials, and sales presentations."

Feds Need To Change

Without a substantial change in the philosophy of federal healthcare regulators, Wood sees little improvement in today's uneven Medicare compliance status quo. "Federal enforcement of Medicare and Medicaid fraud compliance tends to be hands-off, unless violations are obviously egregious," stated Wood. "Thus, when laboratories complain, it seems like no one is listening. It also causes laboratories to stop communicating with federal regulators about practices they see in the marketplace which they consider to be in violation of compliance statutes."

"This lack of effective enforcement or compliance guidance is what causes many of our laboratory and pathology clients to tell me 'we just want a level playing field'," observed Wood. "In general, laboratories or pathology group practices which are owned by pathologists operate with a strong professional philosophy of doing right by

the patient. It's probably an ethic rooted in their training and choice of medicine as a career. But this philosophy of 'doing right' also guides their compliance programs, which tend to be conservative and straightforward.

"Unlike medical professional groups, public companies are organized around different business objectives," continued Wood. "These create different tensions when it comes time to establish compliance programs that may constrain growth or affect profitability.

Compliance Track Record

"Probably the best example of this dichotomy between public healthcare companies and professional medical enterprises is the hospital industry," offered Wood. "Some for-profit hospital corporations have a much different compliance track record than not-for-profit hospitals. The organizational mission of each explains part of this difference."

The range of legal issues which can come into play when a laboratory decides to use the "Waiver of Charges to Managed Care Patients" strategy is extensive. In reviewing these issues, Wood has demonstrated that there can be significant risk attached to this strategy.

Uneven Compliance

Wood has also highlighted the problem of uneven compliance. Without more specific and objective guidelines from federal regulators, and in the absence of any high-profile disciplinary action against laboratories which push the Medicare compliance boundary, this uneven playing field will continue.

Maybe one way to change this situation would be for more laboratories and pathology groups to actively call the attention of federal regulators to situations where non-compliant practices may be occurring. At a minimum, that would regularly remind regulators that existing guidelines lack detail and objectivity. At a maximum, it might actually stir useful enforcement action and create the level compliance playing field that most laboratory managers and pathologists say they prefer. TDR

Contact Jane Pine Wood at 508-385-5227.

"Free Testing" Can Affect Usual Charge Calculations

ONE CONSEQUENCE from using "free testing" is the effect it may have on a laboratory's calculation of "usual and customary" charges under recently-proposed Medicare rules.

"The new formula for determining customary charges requires a laboratory to include the prices it offers to managed care Medicare and Medicaid programs," stated Jane Pine Wood, Attorney and Partner at McDonald Hopkins.

"The situation in Tennessee where Quest Diagnostics is waiving charges for testing it does on TennCare Select patients illustrates this principle," she said. "Our reading of the proposed new rules indicates that we would advise our laboratory clients to include the 'free testing' specimens into the calculation in situations that have characteristics similar to the Quest–TennCare situation.

"Because such testing is done at no charge, it will have a definite impact on the final calculation of 'customary and usual charges' that the proposed guidelines require of laboratories," observed Wood. "Further, it also represents another negative consequence that results when a laboratory uses this 'free testing' strategy in the marketplace."

Where Will "Free Tests" Take the Lab Industry?

Increased use of this marketing strategy could have serious financial consequences

CEO SUMMARY: In the absence of public discussion, continued use of the "free testing" strategy by the nation's more aggressive laboratory companies could trigger some unpleasant consequences that would affect all laboratories and pathology group practices. Five questions, presented here, illustrate how private and public healthcare payers might react to the ongoing use of "free testing."

By Robert Michel

WHEN IT COMES TO THE TOPIC of "free testing," it seems every laboratorian with knowledge of this lab sales and marketing strategy has an opinion.

These opinions can be mostly categorized as either outright opposition to the concept of "free testing" or a belief that the "free testing" strategy has a useful place in the competitive market.

But the use of "free testing" (as allowed by the OIG's "Waiver of Charges to Managed Care Patients fraud alert) has occurred without much public debate within the laboratory profession. That denies the profession the opportunity to better understand the pros and cons before continued use of "free testing" arrangements triggers permanent (and possibly damaging) consequences to both the healthcare system and the laboratory industry.

In fact, so little has appeared in the public space on this topic that there are still lab directors and pathologists who are surprised to discover, for the first time, that there are circumstances where the Medicare program will allow a laboratory to test some specimens from a physician's office for free, in order to gain access to the other specimens, including those from Medicare and Medicaid patients.

Discussion and Debate

To fill this information vacuum and encourage discussion and debate, THE DARK REPORT devoted this issue to the twin topics of "Waiver of Charges to Managed Care Patients" and uneven compliance by some laboratories.

The "free testing" debate should be centered around five basic questions. First, is it smart business for any laboratory to publicly offer "free testing" for a portion of a client-physician's laboratory test referrals, in exchange for access to the balance of that client's test referrals?

Second, what message does the offer of "free testing" for one managed care plan's patients send to other payers in the same region about the value of laboratory testing and the cost to provide such testing? Third, what are the

compliance thresholds for the allowable percent of "free testing," such that if a lab exceeds these thresholds, the "free testing" strategy in that situation is recognized to be a clear violation of Medicare fraud and abuse statutes?

Effect On "Customary Fees"

Fourth, as Medicare takes steps to create more specific calculations for "usual and customary charges," is it unwise for some laboratories to be offering "free testing" in a form that may be noticed by Medicare officials and cause them, at some future time, to justify lower reimbursement because laboratories are willing to perform "free testing" for private payers' beneficiaries? Could this also cause Medicare officials to expand a future definition of "usual and customary" calculations of laboratory test charges to include "free testing" provided to private payers' beneficiaries?

Fifth, could expanded use of "free testing" put those labs using this strategy in the same type of jeopardy that resulted from the charges settled in the OIG's "LabScam" operation ten years ago? At the time when some laboratories first began to create lab test panels and unbundle certain tests in these panels when billing Medicare, regulatory guidance on these points was either vague or non-existent. It was only after federal investigators decided to stop what they considered had become an abusive practice that legal interpretations of these practices became quite specific.

Collectively, laboratories paid more than $1 billion in fines and restitution to the Medicare and Medicaid programs to settle these allegations of Medicare fraud and abuse. If the use of "free testing" was to continue and grow, it is possible that federal healthcare investigators could build a legal argument that the actual implementation of "Waiver of Charges for Managed Care Patients" went beyond the intent of the December 1994 OIG fraud alert. This would place both laboratories and the physician-clients who signed contracts to enter these "free testing" arrangements at risk for claims of Medicare fraud and abuse.

Collectively, these five questions demonstrate that there are potential industry-wide risks that accompany the use of the "free testing" strategy. It would be timely and beneficial for lab industry leaders to address and debate these topics in both public forums and the lab industry press. THE DARK REPORT is willing to devote time during the upcoming *Executive War College*, scheduled for April 27-28, 2004 in New Orleans.

Shaping The Debate

Those laboratory directors and pathologists interested in helping to develop this topic should contact our offices. The phone number and e-mail address is listed below. Also, to better evaluate the potential impact of this growing trend, it would be helpful to gather examples of how "free testing" is being used in the laboratory marketplace. Laboratories with such information should feel free to provide information in full confidence.

If "free testing" has the potential to trigger a variety of negative financial consequences for the laboratory professional several years down the road, then timely research, discussion, and debate about this issue is important. Such debate may forestall inappropriate use of "free testing." If this is the eventual outcome, it would prevent the "deja vu" of repeating the mistakes of the below-cost pricing for capitated HMO lab testing contracts that occurred in the lab industry some 10 to 15 years ago. **TDR**

Contact Robert L. Michel at 512-264-7103 or e-mail: labletter@aol.com.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Lab-Interlink Inc. of Omaha, Nebraska is heading to bankruptcy court. On November 24, the day before Thanksgiving, the company laid off 50 employees. Rodney Markin, M.D., Ph.D., Company founder and Chairman stated that an expected $1 million payment by a prospective buyer had not materialized that day. The money was to have covered payroll and operating expenses for November. Only four employees remain. Negotiations with the buyer continue. Markin says Lab-Interlink needs between $8 million and $12 million in new cash to resume operations. Lab-Interlink sells a line of laboratory automation equipment and software.

NEW INDIANAPOLIS LAB

Clarian Health Partners of Indianapolis, Indiana is building a new off-site core laboratory to serve the three hospitals in its health system, as well as several other hospitals in the area. The lab will be 150,000 square feet. This lab may form the basis for an invigorated lab outreach program in the Indianapolis area.

DNA ANALYSIS HELPS IN PENNSYLVANIA HEPATITIS OUTBREAK

Molecular diagnostics continues to make advances. With 520 confirmed cases and three deaths, the hepatitis A outbreak in the Pittsburgh area made plenty of headlines. New DNA-based tools have aided epidemiologists in their investigation. Last week, the **Centers for Disease Control and Prevention** (CDC) announced that, based on DNA analysis, it was highly probable that the Pittsburgh outbreak was caused by a single food source. The CDC also stated that it could find no food handlers who transmitted the disease.

ADD TO: *Hepatitis A*

These findings are significant, because several employees at the Beaver Valley **Chi-Chi's Restaurant**, source of the hepatitis infection were infected. DNA analysis of viral samples from outbreaks in Tennessee and Georgia showed enough similarities that officials believe one food is the source of the outbreak in the three areas. Imported green onions are suspected, but this has not been confirmed. The use of molecular technologies to match viral strains within an epidemic and across several epidemics, in a matter of weeks, shows the potential of molecular diagnostics to radically change existing standards of practice.

TRANSITIONS

• **Quest Diagnostics Incorporated** announced that Chairman and CEO Kenneth W. Freeman will transfer CEO responsibilities to Surya N. Mohapatra, Ph.D., who is current President and COO. The transition will happen by spring 2004. Freeman will remain as Chairman of the Board of Directors.

• **Esoterix, Inc.** has a new Vice President and General Manager for its oncology division. Bill Tilton, formerly with **DIANON Systems** and **UroCor** recently accepted the position and will work from Esoterix' Austin, Texas headquarters.

That's all the insider intelligence for this report. Look for the next briefing on Monday, December 22, 2003

EXECUTIVE WAR COLLEGE

April 27-28, 2004 • Astor Crowne Plaza Hotel • New Orleans

Molecular Diagnostics: Today's Reality and Tomorrow's Revolution

Twin trends are driving change in laboratories and pathology practices. In management, Six Sigma and Lean methods are helping lab administrators and pathologists revamp their labs and pick up gains of 50% in TAT, productivity, and quality. In medicine, the earliest applications of molecular technology in diagnostics are improving diagnostic accuracy and changing the relationship between laboratories and the clinicians they service. Learn first-hand from early-adopter laboratories!

Program details available soon!

visit darkreport.com

UPCOMING...

- ***TDR's Annual Review of the Lab Industry's Ten Biggest Stories of 2003.***
- ***More Bankruptcy Among Lab Industry Vendors.***
- ***New and Evolving Legal Landmines For Clinical Laboratories.***

visit us at:
www.darkreport.com