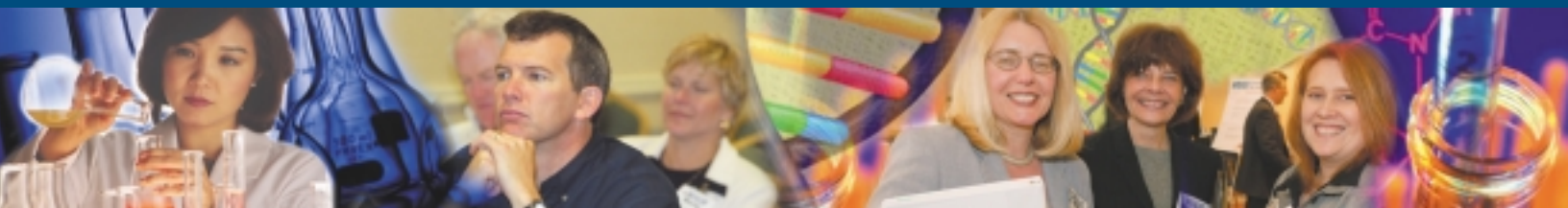


*"It's the New Decade's Most Important Meeting in Lab Management...  
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# MOLECULAR DIAGNOSTICS!

**Today's Reality and Tomorrow's Revolution**

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



## Get the inside story on all this and more!

- Molecular testing programs at community hospital labs
- New generation automation in histology laboratories
- Secrets to getting paid for molecular lab tests
- How labs are using Six Sigma and Lean to post gains of 50% in TAT, productivity, and quality
- Candid Insights on Medicare compliance and abuses in the competitive outreach marketplace
- Practical advice on when labs should "make" and when labs should "buy" molecular tests
- Do's and Don'ts with vendors when buying molecular test kits
- Direct Access Testing (DAT) in partnership with retailers

## PLUS SPECIAL THIS YEAR!

### **Molecular Diagnostics For Laboratory Leaders**

Join our international experts for a one-day intensive overview. Get the real scoop on molecular diagnostics, from technology, clinical applications, and reimbursement to regulatory issues and more. (See pages 8-9)

**Special thanks and acknowledgement to corporate benefactors and sponsors:**



**DADE BEHRING**



**2004 EXECUTIVE  
WAR COLLEGE**  
On Lab and Pathology Management

Presented and Produced by: **THE DARK REPORT**

Continuing Education Units Provided by: *American Association of Clinical Chemistry*

**To register or for more information go to: [www.darkreport.com](http://www.darkreport.com) or call 888-291-2525**

- How molecular technologies are acting swiftly to reshape clinical laboratory services.
- Revealing look at how patient safety is causing physicians to pull tests out from core laboratories.
- Ways for pathology groups to generate additional revenue from value-added anatomic pathology services.
- New opportunities for community hospitals to make money from molecular-based testing.
- Proven techniques for getting paid on molecular-based laboratory tests.
- Medicare compliance: new strategies to deal with competitive disadvantages in outreach market.
- For community hospitals: best ways to develop the right “make or buy” decision on molecular testing.
- Big gains from early-adopter histology labs and pathology groups using next-generation automation.

**Why this year, more than ever, you'll want to attend the largest laboratory management summit in the lab industry!**



*“Every laboratory will be deeply touched by two potent developments. First is the growing role of molecular diagnostics in everyday testing. Second are the remarkable benefits Lean and Six Sigma deliver when applied in high-volume core laboratories. Join us on April 27-28 to learn everything you need to keep your laboratory on the winning track!”*

*—Robert L. Michel  
War College Founder*

## EXECUTIVE MEMORANDUM

TO: Laboratory and Pathology Professionals  
From: Robert L. Michel, Editor, *THE DARK REPORT*  
Re: How *EXECUTIVE WAR COLLEGE 2004* helps you deal with molecular diagnostics in demanding times

Molecular diagnostics is the single biggest threat—and opportunity—confronting the nation's laboratories and pathology groups today. Yet a growing number of community hospital laboratories have robust molecular testing programs, and some even make money!

To help you guide your laboratory or pathology group into the fast-developing world of molecular diagnostics, we've assembled the nation's leaders in all aspects of clinical molecular diagnostics. Learn directly from laboratories already providing daily molecular testing services to clinicians. Understand why some molecular assays are ready for prime time, but others are not.

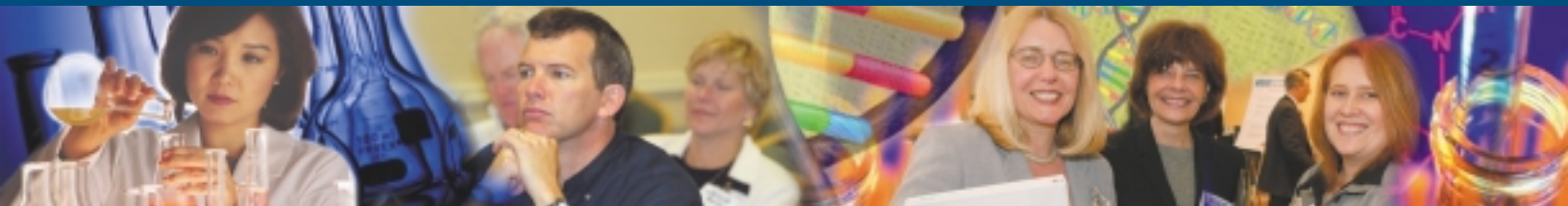
You'll have an unprecedented experience at this year's *Executive War College*. We've diligently searched the laboratory universe to identify pathologists, laboratory directors, and vendors who are breaking the right ground in molecular diagnostics. You'll meet them personally. You'll get the right answers to your important questions. Most importantly, you'll build the personal network that's essential to every successful laboratory.

Along with molecular diagnostics, this year's hot topic is how hospital laboratories such as those at Fairview Health Services in Minneapolis or West Tennessee Healthcare in Jackson, are using quality management methods such as Lean and Six Sigma to slash TAT by 50% and boost productivity by up to 60%—while delivering higher quality and enhanced laboratory services. You won't want to miss learning why these methods are so effective—and why they can work in any laboratory, including yours!

Add it up! Your lab is facing difficult decisions about molecular diagnostics. Your lab is seeking ways to accomplish more with shrinking budgets. Your lab needs the right automation solutions. Our *Executive War College* has the answers you seek on these and other management challenges. Join us in New Orleans on April 27-28 and get the knowledge and insight you need to increase the success of your laboratory!

Best,

Robert L. Michel  
War College Founder and Host



## Discover, challenge... and meet with some of the nation's most influential pathologists, laboratory administrators, and executives

### Outstanding laboratory leaders make this a true "summit":

*Executive War College 2004* gathers the best of the best. These are among the people you'll meet and hear—sharing best practices in laboratory and pathology management:

**Rick Panning**, President, Laboratory Services, Fairview Health Services

**Azorides Morales, M.D.**, Chief of Pathology Services, University of Miami

**Ronald L. Weiss, M.D.**, President & COO, ARUP Laboratories

**Mark Hughes**, Senior Consultant, Enterprise Analysis Consultants

**Fred Plapp, M.D., Ph.D.**, Medical Director of Laboratories, St. Luke's Regional Laboratories

**Kenneth J. Bloom, M.D.**, Senior Medical Director, US Labs, Inc.

**Michael J. Becich, M.D, Ph.D.**, Chief of Pathology Laboratories, UPMC Health System

**David Wilkinson, M.D., Ph.D.**, Chairman of the Department of Pathology, VCU Health System

**William Clarke, Ph.D.**, Director of Drug Assay Laboratory, Johns Hopkins University Medical Center

**Stan Schofield**, President, NorDX Laboratories

**John McCarty**, Chief Financial Officer, LabOne

**Priscilla R. Cherry**, Director, Laboratory Consulting, Premier, Inc.,

**David Hicks, M.D.**, Section Head of Surgical Pathology, Cleveland Clinic

**Cynthia K. French, Ph.D.**, Chief Scientific Officer, Specialty Laboratories, Inc.

**Paul Sohmer, M.D.**, President & CEO, TriPath Imaging, Inc.

### Provocative keynoters spur you to learn, think... and grow

#### **Thomas M. Grogan, M.D.** of Ventana Medical Systems, Inc. on **Why Next-Generation Technologies in Automation and Molecular Diagnostics Will Energize the Anatomic Pathology Profession**

All signs point to a revolution in the histology laboratory and its relationship to anatomic pathology services. In a *War College* exclusive, this esteemed pathologist-entrepreneur shares his strategic view of the coming changes. This is a "must hear" presentation for both lab managers and pathologists, because it describes how clinical labs and pathology labs will become increasingly integrated, automated, and molecular.



#### **Tiffany Olson** of Roche Diagnostics, Inc. on **Molecular Diagnostics' Future from the IVD Manufacturer's Perspective**

In the clinical laboratory, molecular technologies are expected to find wide application in diagnostic testing. Explore the new roles that molecular tests will play in medicine, from predictive genetic tests to pharmacogenomics and theranostics. Get inside the strategic perspectives shaping molecular strategies at one of the world's largest firms with a major presence in both pharmaceutical drugs and in vitro diagnostic testing.



#### **Gene Pawlick, M.D.** of Kaiser Permanente No. Calif. on **Rapid transition to DNA-based cervical cancer screening and the laboratory's role in physician and patient education**

Kaiser Permanente Northern California is adopting new cervical cancer screening guidelines. Among other things, it means that its regional laboratory is now actively gearing up to perform 400,000 molecular HPV tests per year! (Compared to 5,000 HPV tests in 2003.) Learn the amazing story of how this laboratory is using both new automated instruments and additional medical technologist resources to handle this demand. It's a first-hand look at how a broad-based screening program using molecular diagnostics changes both the laboratory and its working relationship with referring clinicians.



#### **Leo Serrano** of West Tennessee Healthcare on **Confessions of a Sinner: "I Automated Bad Work Processes in My Core Laboratory"**

When the laboratory division at West Tennessee Healthcare built a state-of-the-art automated core laboratory in 2000, it believed it was doing the best thing to improve services. As the new laboratory delivered substantial improvements in test turnaround time, labor productivity, and lower costs, everyone was delighted. However, just months ago, the laboratory division did a "Lean" makeover of the work processes in its new, automated core chemistry/hematology laboratory. The Lean makeover delivered a further reduction in TAT of 42%, from 71 minutes down to 41 minutes. Labor inputs were slashed by an additional 35% even as the lab's footprint was reduced by one-third, from 60,000 square feet to 40,000.



#### **James D. Cross, M.D.** of Aetna, Inc. on **Investing in Testing: How New Molecular-Based Assays Are Evaluated for Coverage and Reimbursement Decisions**

As new molecular tests come to market, labs need to understand how health plans make decisions to accept tests for coverage and establish reimbursement. Dr. Cross oversees Aetna's development and maintenance of coding logic, clinical and coverage policies, case management, customer service efforts, and reimbursement policy. Like most laboratories, Aetna is concerned about the coming tidal wave of lab tests based on molecular technologies and how they affect healthcare outcomes and the cost of care. Here's a rare opportunity for lab directors and pathologists to hear, first-hand, from one of the insurance industry's leading policy makers, about the concerns and strategies payers have relating to molecular diagnostics.



## Monday, April 26

4:00 pm–6:00 pm

### Special Sessions by Invitation

*Bayer Diagnostics*

*Dade Behring*

*Ortho-Clinical Diagnostics*

6:30 pm–8:30 pm

### Early Registration

*Get Acquainted Reception with Refreshments*

## Tuesday, April 27

8:15 am–9:00 am

### Molecular Meets Lean: Twin Trends Leading Laboratories in New Directions

*Robert L. Michel, Editor, THE DARK REPORT, Spicewood, TX*

Molecular diagnostics and Lean management methods are twin trends already reshaping the form and structure of clinical laboratories. Explore how early-adopter labs are reconfiguring core laboratory facilities. Learn what their experience teaches about how molecular-based testing and Lean management methods will change the way laboratory testing services are organized and delivered to clinicians.

9:00 am–9:45 am

### Case Study: Fairview Health Services, Minneapolis, MN

(Aggressive deployment of Six Sigma and Lean Methods in multi-hospital laboratory)

*Rick Panning, President, Laboratory Services*

With eight hospitals, including the University of Minnesota Medical Center, Fairview Health Services is among the largest IDNs (integrated delivery network) in the United States. One year ago, its laboratory division was among the nation's first to use the management methods of Six Sigma and Lean to restructure the high volume core chemistry/hematology laboratory at its 390-bed Southdale Hospital. In just 16 weeks, the Lean team slashed average turnaround time by 50%. This 50% improvement was matched by comparable gains in labor productivity, error reduction, and enhanced lab testing services. Administration considered the project so successful that Lean teams have since been launched in three other hospital labs, a histology lab, and in other clinical areas of Fairview Health Services.

10:15 am–11:15 am

### Case Study—Confessions of a Sinner: "I Automated Bad Work Processes in My Core Laboratory" (West Tennessee Healthcare, Jackson, TN)

(Construction of a new, fully-automated core laboratory was followed months later by a comprehensive Lean makeover of that brand-new core laboratory)

*Leo Serrano, Administrative Director, Laboratory Services*

(See description on page 3.)

11:15 am–12:00 pm

### Case Study: Kaiser Permanente Northern California Regional Laboratory, Oakland, CA

(Rapid transition to DNA-based cervical cancer screening and the laboratory's role in physician and patient education concerning new clinical guidelines)

*Gene Pawlick, M.D., Director, Regional Laboratory*  
(See description on page 3.)

1:15 pm–2:00 pm

### Case Study: Jackson Memorial Hospital / University of Miami Medical School, Miami, FL

(Changing histology operations and using new technology to automate and create "same day" and "point-of-care" anatomic pathology services)

*Azorides Morales, M.D., Chief of Pathology Services*  
Here's one of the most exciting stories of 2004.

Using new technology that automates several aspects of the histology laboratory, Dr. Morales has succeeded in creating a "same day" turnaround capability at Jackson Memorial Hospital. Currently 70% of the specimens referred to his pathology laboratory are signed out the same day. Even more stunning is what can be called the "point-of-care" (POC) histology laboratory that was built upstairs next to the oncology ward and its surgical suites. Supported by real-time histology processing of specimens coming from these surgical suites, pathologists are currently providing diagnoses to the referring physicians even as patients are wheeled out of the recovery room. Gain valuable insights into how new technologies are about to transform long-standing work processes in the anatomic pathology profession.

2:00 pm–2:50 pm

### Concurrent Breakout Sessions 1

#### A. Who's Doing Clinical Molecular Testing? The Real Scoop on Which Labs and Which Molecular Tests Are Actually in the Market

*Mark Hughes, Senior Consultant, Enterprise Analysis Consultants, Stamford, CT*

Here's definitive information on the state of clinical molecular testing. Enterprise Analysis Consultants (EAC) recently completed the laboratory industry's first comprehensive survey of 500 laboratories. In a *War College* exclusive, attendees will learn whether or not hospital laboratories are successfully operating molecular testing programs, what types of molecular assays are offered in these programs, and predictions about specific molecular technologies expected to gain clinical acceptance in the coming 24 months.

#### B. Using Lab Test Data to Drive Improvements in Both Clinical Outcomes and Test Utilization

*Fred Plapp, M.D., Ph.D., Medical Director of Laboratories, St. Luke's Regional Laboratories, Kansas City, MO*

Learn how clinical pathologists at St. Luke's Health System play a key role in improving the laboratory's

contribution to improved clinical outcomes at a lower overall cost per healthcare encounter. It's a powerful demonstration of how closer collaboration between pathologists and clinicians pays big dividends—to patients, to physicians, and to the hospital. St. Luke's, a Baldrige Quality Award winner this year, can document the improvements triggered by better use of laboratory tests and the timely introduction of new assays.

### C. How to Fund Molecular Testing Programs: Tapping Sources of Start-Up Capital and Reimbursement for Clinical Testing Services

*Kenneth J. Bloom, M.D., Senior Medical Director, US Labs, Inc., Irvine, CA*

With years of experience at creating and managing molecular testing programs at such noted laboratories as Rush-Presbyterian Medical System in Chicago and US Labs, Inc., Bloom has a unique perspective on how to fund such testing programs. Explore how research grants and clinical studies can provide working capital to fund the creation of a molecular testing laboratory. Learn how payers make coverage decisions and establish reimbursement levels for new molecular assays. This is a practical, hands-on look at what academic center labs and community hospital laboratories must do to establish a clinical molecular program which is both clinically and financially successful.

### D. Anatomic Pathology's 3-Way Informatics Collision of Telepathology, Digital Imaging, and the Electronic Medical Record (EMR)

*Michael J. Becich, M.D., Ph.D., UPMC Health System, Pittsburgh, Pennsylvania*

Learn about the pathology profession's evolution toward the fully-digital world. Dr. Becich provides up-to-the-minute intelligence on how various informatics technologies are coming together and changing the way innovative pathology groups operate. UPMC has been moving swiftly to digitize all anatomic pathology images. The health system's goal is to fully digitalize all clinical images (including radiology) to support an electronic patient medical record. Learn how the UPMC pathology department has "gone electronic" with different aspects of its daily work processes, and what impact this is having on how its anatomic pathologists provide services to referring clinicians.

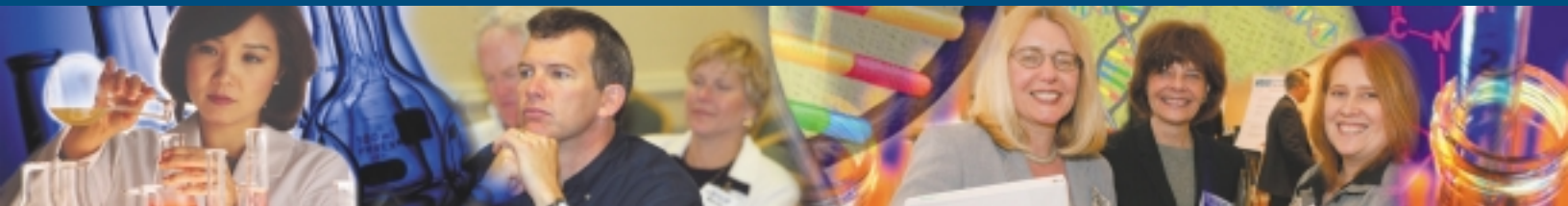
3:00 pm–3:50 pm

### Concurrent Breakout Sessions 2

#### E. Secrets of the Economically-Viable Molecular Testing Program in an Academic Center Laboratory

*David Wilkinson, M.D., Ph.D., Chairman of the Department of Pathology, and Ann L. Harris, Outreach Program Manager, VCU Health System, Richmond, VA*

One of the earliest molecular testing programs to emerge in the last decade was at the Medical College of Virginia (MCV). Starting with HIV mutation and



viral load testing, MCV learned how to offer molecular tests that generated adequate reimbursement. Discover how the growth of profitable molecular testing allowed MCV to build a state-of-the-art molecular laboratory by the end of the decade. Get first-hand information about the secrets and practical experience of what is required to establish a molecular testing program that generates revenue, as well as pitfalls to avoid.

### **F. Proven Selling Methods for Small Pathology Groups to Market Subspecialty Skills Nationally**

**Peter Kolbeck, M.D.,** *President and Pathologist, Path Logic, Fair Oaks, CA*

Starting as a one-pathologist group, Peter Kolbeck, M.D. has developed a national business as a subspecialist in renal pathology. Just five years ago, Dr. Kolbeck launched a dedicated sales and marketing effort to add new clients. His group of eight pathologists now handles specimens from four states and the business continues to expand. Get the inside story on how a determined, focused sales program can grow a profitable national AP business, currently sustained by three full-time sales representatives.

### **G. Almost Primetime for Proteomics: Early Lessons in Oncology from Johns Hopkins University Medical Center**

**William Clarke, Ph.D.,** *Director Drug Assay Laboratory, Johns Hopkins University Medical Center, Baltimore, MD*

Many experts expect the most powerful diagnostic information will come from protein-based assays, not labs tests built on DNA or RNA analysis. Here's a rare opportunity to learn about the break-through discoveries achieved by Dr. Chan and his group, and the rapid speed by which they are being converted into diagnostic tests for use in clinical laboratories.

### **H. Understanding the OIG: Insights and Advice on How Labs Can Cope With Aggressive Compliance Practices in the Competitive Lab Services Marketplace**

**Kevin G. McAnaney, Esq.,** *Law offices of Kevin G. McAnaney, Washington, DC and Jeffery J. Sherrin, Esq., O'Connell and Aronowitz, Albany, NY*

Here's a rare opportunity to peek inside the OIG and learn how the agency responds to Medicare compliance issues. McAnaney served as the Chief of the Industry Guidance Branch of the Office of Counsel to the Inspector General from its creation in 1997 until May, 2003. McAnaney and Sherrin have extensive experience in Medicare compliance

issues and, more specifically, how laboratories are affected by Medicare regulations and statutes.

**4:00 pm–4:50 pm**

### **Concurrent Breakout Sessions 3**

#### **I. Getting Your Best Deal from Molecular Test Vendors: How One Health System Laboratory Negotiates Tough Terms**

**Stan Schofield,** *President, NorDX Laboratories, Scarborough, ME*

There are many reimbursement uncertainties connected to molecular testing. For that reason, NorDX Laboratories has a simple strategy when it negotiates contracts. Molecular vendors must partner with NorDX, with contract terms dependent on favorable coverage decisions by payers and adequate reimbursement levels. This is doubly important to NorDX, because it must serve the clinical missions of its hospital owners while providing competitive lab test services to its outreach clients. Learn effective techniques for negotiating win-win contracts with suppliers of molecular tests.

#### **J. Using Value-Added Services in Both Clinical Pathology and Anatomic Pathology to Boost Overall Laboratory Reimbursement**

**F. Michael Walsh, M.D.,** *Chairman & CEO, Consultants in Laboratory Medicine, Toledo, Ohio*

Facing a yearly squeeze on reimbursement by Medicare and private payers, Consultants in Laboratory Medicine (CLM) adopted a new strategy: re-organize the clinical focus of its pathologists to increase the added-value of its services—to both clinicians and payers. To accomplish this strategy, CLM has created a new set of informatics-based tools that CLM's clinical and anatomic pathologists use in clinical consults with referring physicians. It's a fascinating look at how laboratory medicine gains a new level of respect—and reasonable reimbursement—when the laboratory moves past simply reporting lab test results and wraps those results in a richer package of laboratory information.

#### **K. Capturing New Physician-Clients: Service Menu Enhancements that Accelerate Laboratory Outreach Success**

**John Mazzei,** *Executive Director, Memphis Pathology Laboratory, Memphis, TN*

It was just 18 months ago when Memphis Pathology Laboratories (MPL), a joint venture between Baptist Health System and MDS Laboratories, Inc., introduced several new services to its client physicians, including a Web browser-based information system for test orders and test results. The new service package sparked a sales boom in new client accounts. Moreover, this out-

reach success encouraged another health system to merge its outreach program into MPL, allowing it to build a new, state-of-the-art laboratory facility. Here's a compelling look at how MPL energized its sales program, even while using the browser-based lab test order/results system to drive operational improvements within the laboratory.

#### **L. Medicare Compliance: What's Really Happening Among Competing Laboratories in the Lab Testing Marketplace**

**John McCarty,** *Chief Financial Officer, LabOne, Inc., Lenexa, KS, and Jane Pine Wood, Esq., Partner, MacDonald Hopkins, Cleveland, OH*

Get insights into the geographical differences and similarities of laboratory compliance with Medicare/Medicaid regulations and statutes.

Across the country, local laboratories see competitive practices they consider in violation of fraud, anti-kickback, and other compliance requirements. Expect candid talk about what's happening in the marketplace, what's not happening in regulatory enforcement, and the most effective strategies laboratories can pursue to stay in compliance without losing competitive advantage to those labs willing to push the compliance boundary.

**5:00 pm–5:45 pm**

#### **Imminent Revolution: Why Molecular Diagnostics Combined with Lean Management Methods Will Radically Transform Today's Laboratories**

**Moderator: Robert Michel; Panelists: Rick Panning, Gene Pawlick, M.D., Thomas Grogan, M.D., Michael Becich, M.D.**

This session pulls together the presentations of the day. Panelists will offer their insights, recommendations, and predictions about how the twin trends of molecular diagnostics and Lean quality management systems may reshape existing laboratory business models. Armed with their own personal experience, expect strong opinions and thoughtful pronouncements on how the near-term future will unfold for clinical laboratories and anatomic pathology groups.

**5:45 pm–7:45 pm**

#### **Reception**



## Wednesday, April 28

8:00 am-8:40 am

### Molecular Diagnostics' Future from the IVD Manufacturer's Perspective

**Tiffany Olson**, Vice President-Molecular Diagnostics

(See description on page 3.)

8:40 am-9:25 am

### Why Next-Generation Technologies in Automation and Molecular Testing Will Energize the Anatomic Pathology Profession

**Thomas M. Grogan, M.D.**, Chairman Emeritus, Chief Scientific Officer, Ventana Medical Systems, Inc., Tucson, AZ

(See description on page 3.)

9:25 am-10:05 am

### Patients, Payers, & Employers Respond to Genetic and Proteomic Testing: Insights and Lessons from Genzyme's Experience

**Glenn Miller, Ph.D.**, Scientific Director, Genzyme Genetics, Westborough, MA

There is plenty of speculation about how patients, payers, and employers will respond to genetic testing and the secrets it can reveal about an individual's existing and future health. At Genzyme Genetics, years of experience in offering genetic testing in prenatal, oncology, and several other areas of medicine have helped answer some of these questions. Explore what this pioneering company has learned about how patients and payers react to molecular diagnostics. Learn how payers make coverage and reimbursement decisions. Learn which molecular technologies Genzyme expects will find early and fast acceptance among clinicians.

10:25 am-11:05 am

### Investing in Testing: How New Molecular-Based Assays Are Evaluated for Coverage and Reimbursement Decisions

**James D. Cross, M.D.**, National Medical Director, Aetna, Inc., Largo, M.D.

(See description on page 3.)

11:05 am-11:50 am

### Clinical Scoring of Hospital Inpatients Creates Substantial New Value from Laboratory Test Data

**Richard S. Johannes, M.D.**, Vice President of Medical Affairs, MediQual, Cardinal Health, Marlborough, MA

What if, with a high degree of accuracy and at the time of admission, your hospital could predict the length-of-stay (LOS) and mortality of patients with serious health conditions?

MediQual has developed just such a tool. Based on studies of 25 million individual patient records and information from 300 hospitals, MediQual has developed predictive models now used by subscriber hospitals. Laboratory test data is one of the most essential components for predicting the likely LOS and mortality of individual patients. Explore this new dimension of medicine, which analyzes lab test data in conjunction with other information, and gives clinicians additional diagnostic insights.

1:00 pm-1:50 pm

### Concurrent Breakout Sessions 5 M. Direct Access Testing (DAT) Successes at Ohio State University Medical Center

**Harry Pukay-Martin**, General Manager & CFO, and **Amy Gewirtz, M.D.**, Associate Professor, Clinical Pathology, Ohio State University Medical Center, Columbus, OH

It's a different twist on the early efforts by laboratories to establish direct access testing (DAT) programs that connect with consumers. At Ohio State University Medical Center (OSUMC), an ongoing partnership between the health system and Kroger Grocery Stores (with national headquarters in Columbus, OH) opened the door for the laboratory at OSUMC to establish a DAT program in the pharmacies of Kroger grocery stores in the Columbus area. Get an inside peek at how this collaboration with a major retailer brings different benefits—and challenges—to direct access testing programs. Learn why, in Columbus, a national laboratory, in partnership with a national drug store chain, decided to terminate its own DAT program, even as the OSUMC Lab-Kroger DAT collaboration continues.

### N. Moving to National Measures of Laboratory Quality: CDC's Institute of Quality in Laboratory Medicine (IQLM) Prepares to Raise the Bar in American Laboratories

**Ana Stankovic, M.D., Ph.D.**, Worldwide Medical Director, Pre-Analytical Systems, Becton Dickinson, Franklin Lakes, NJ

This fall, the CDC's newly-created Institute of Quality in Laboratory Medicine (IQLM) expects to issue a report on the national quality of laboratory testing services. This report will be supported by the introduction of laboratory quality measures. Annually, laboratories will be polled on their performance in these quality measures. Results will be tabulated and the IQLM will report to the nation on the cumulative improvement or decline in laboratory quality during the previous year. National laboratory quality awards will also be announced this fall. This initiative is designed to encourage significant changes in how laboratories eliminate errors, improve quality, and raise the clinical effectiveness of the lab tests they provide to clinicians.

### O. Potent Ways to Use External Lab Benchmarks to Accelerate Productivity Gains

**Kathy Durr**, Administrative Director, Abington Memorial Hospital, Abington, PA

Every hospital laboratory strives to do more with less. But few laboratories have confidence and confirmation they manage their laboratory in an optimum fashion. One reason is because many programs to share lab productivity are flawed. Learn how Abington Hospital's laboratory uses external benchmarking programs to drive sustained improvements in both productivity and overall laboratory performance. One unusual aspect is that Abington Hospital actively monitors the performance of all clinical departments involving two universal variables: "average worked hours per billable procedure" and "average cost per billable procedure." This means the laboratory at Abington Hospital is tracking its accomplishments not only against its external laboratory benchmarks, but also against other clinical departments within the hospital.

### P. Lab Vendors As a Value-Added Resource: Surprise Lessons From Premier's Unusual Collaboration between IVD Companies and Their Laboratory Customers

**Priscilla R. Cherry**, Director, Laboratory Consulting, Premier, Inc., Charlotte, NC

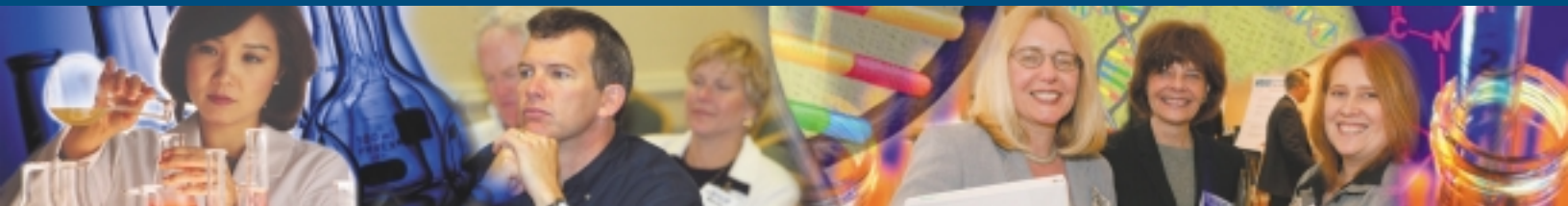
When laboratories buy instruments and reagents, they often fail to negotiate beyond lowest price and specific service needs when selecting a vendor. Premier, Inc., one of the nation's largest group purchasing organizations (GPO), recently completed a major project to demonstrate how IVD vendors and their laboratory customers could collaborate to dramatically improve a lab's performance in a variety of ways. Called the "Laboratory Optimization Project" (LOP), it involved small, medium, and large hospital laboratories. Participants surprised even themselves at how effective collaboration could improve productivity, reduce costs, streamline work processes, and boost morale within the laboratory. In some cases gains of 25% to 50% were achieved. Learn proven ways a laboratory of any size can harvest major benefits by asking IVD vendors to provide more than just instruments and reagents.

2:00 pm-2:50 pm

### Concurrent Breakout Sessions 5 Q. Avoiding the Molecular Test Budget-Buster at Community Hospital Labs: Lessons from the Ten-Year "Make or Refer" Experience at St. Luke's Hospital

**Jane Rachel, M.D.**, Director, Flow Cytometry and Molecular Diagnostics, St. Luke's Regional Laboratories, Kansas City, MO

Is molecular testing considered a "budget-buster" at your laboratory? Whether the question is when



to refer such tests versus whether to set up and run them internally, no easy answers exist. However, through trial and error, some innovative laboratories have crafted workable strategies and techniques. Come and listen to how St. Luke's Hospital has used positive and negative experiences to develop a substantial molecular testing program, yet one that is both clinically potent and cost effective. Learn how clinicians are involved in decisions to offer molecular tests and the management methods used to determine when tests should be referred and when tests can be set up within the laboratory. Expect surprises, practical experience, and useful insights from this rare opportunity.

### **R. Harvesting Major Gains in Histology and Anatomic Pathology: The Cleveland Clinic Experience**

**David Hicks, M.D.**, *Section Head of Surgical Pathology, Cleveland Clinic, Cleveland, OH*  
Histology is rapidly becoming a high-profile management issue for most pathologists and laboratory directors. An acute shortage of histotechnologists makes it tough for the lab to have adequate staffing to handle an ever-growing volume of specimens. The growing test menu adds further stress on staff. At the same time, new automation solutions for the histology laboratory add a new layer of management complexity. That's why the ongoing, two-year project to reassess and restructure histology operations at the Cleveland Clinic provides valuable lessons and insights. Explore how this histology lab handles 80,000 specimens and 75,000 special-staining procedures annually. Master the lessons of what to do and what not to do in responding to the ever-growing number of molecular tests with a limited supply of histotechnologists.

### **S. Employers, Payers, and Patients Push For Major Change: Essential Insights about Healthcare's "New" Consumers**

**Kerry Kaplan**, *President, Healthcare Connections, Natick, MA*

For the first time in several decades, there is alignment among employers, government and private payers, and patients about the need for healthcare to change. As a result, the relationship patients have with their physicians—and laboratories—is already changing. As a consultant to some of the nation's largest corporations and health insurers, Kaplan has a unique perspective into how and why the buyers of healthcare—specifically payers, patients, and employers—are changing long-standing practices and adopting new approaches. Explore the startling changes that lie ahead for clinical laboratories and pathology group practices. These include patients "buying" care with direct debit cards, provider

networks that exclude physicians, hospitals, and labs that get poor healthcare outcomes, and the need to score high in patient satisfaction surveys. Here's a revealing look at what types of different, patient-centric revenue models will alter the way laboratories and other providers retain access to patients.

### **T. POCT: New Clinical Standards Cause Clinicians to Pull Tests Out of the Core Lab**

**Robert H. Christenson, Ph.D.**, *Director, Rapid Response Laboratories, University of Maryland School of Medicine, Baltimore, MD*

There's a new twist to the ongoing challenges and problems of point-of-care testing (POCT). Introduction of new clinical standards is motivating physicians to demand testing be done closer to the patient. Effectively, it means that physicians have valid reasons to "pull" specific tests out of the core laboratory and have them performed in near-patient and POCT settings. To address this change, the University of Maryland Medical School laboratories found it necessary to develop a different relationship with clinicians and establish new pathways for making POCT decisions, introducing these tests, and supporting the ongoing utilization of such testing. Find out which POCT program landmines can derail strong working relationships between the labora-

tory and the clinicians it serves. Learn how this laboratory developed a win-win program to handle current (and future) requests for POC testing by physicians in the health system.

**3:00 pm-3:30 pm**

### **Creating the Perfect Molecular Testing Program: Key Lessons from the Executive War College Faculty**

**Robert L. Michel**, *Editor-In-Chief, THE DARK REPORT*

With 40 presentations and lots of new information about the responses of early adopter laboratories to both molecular diagnostics and quality management techniques, it can be daunting to identify key management themes and to understand their impact on laboratory operations. This presentation strives to provide clarity and insight. It identifies essential steps laboratories should take to keep their operations and lab test services focused to provide client physicians value-added laboratory medicine services. This session's razor-sharp analysis gives attendees the perfect summary to the full scope of knowledge presented at this year's *Executive War College*.

**3:30 pm**

**EXECUTIVE WAR COLLEGE ends**



Optional Full Day Program on Thursday, April 29

## *Molecular Diagnostics for Laboratory Leaders!*

*A Comprehensive Day on Technology,  
Trends, Regulatory Issues, Reimbursement*

**It couldn't be more timely!**

### **A special one-day program on molecular diagnostics for clinical labs and pathology groups**

Even as you read this, the leading edge of the genetic revolution is arriving in clinical laboratories and anatomic pathology group practices in the United States and Canada. New diagnostic tests based on molecular technologies are reaching the clinical marketplace.

Molecular diagnostics is both a major threat and a major opportunity. To help you sort through the important issues, we've invited a panel of molecular experts to share their insights, predictions, and recommendations. In just one day, you'll get the full range of information you need to successfully guide your laboratory through the early stages of the molecular revolution.

It's your best opportunity to get the inside scoop on molecular diagnostics. Learn how billion-dollar IVD companies view the molecular diagnostics marketplace. Explore the ways that molecular technologies will reshape the historical roles of clinical laboratories and anatomic pathology. Understand the critical issues involving regulatory requirements and payer reimbursement decisions.

You can't afford to miss this essential one-day session! It's your best opportunity to sort through the clutter and hype. At day's end, you'll have the knowledge you needed to develop a successful—and profitable—molecular testing program in your laboratory!

- Understand how the world's largest IVD manufacturers expect molecular technologies to change clinical laboratory services.
- Learn about the expected impact molecular assays will have on existing anatomic pathology services.
- Develop a strategic vision for molecular diagnostics in your laboratory.
- Explore the regulatory issues surrounding molecular diagnostics in clinical laboratories.

**REGISTER BY MARCH 29  
FOR EARLY-BIRD SAVINGS!**







## Agenda

▶ register separately for Thursday, April 29 • 8:00 a.m – 4:45 p.m.

# Molecular Diagnostics for Laboratory Leaders

8:00 am–8:30 am

## Getting Grounded in the Molecular World: What to Watch and When to Act

**Cynthia K. French, Ph.D.**, Chief Scientific Officer, Specialty Laboratories, Inc., Santa Monica, CA.

Here's a great start to an exceptional day of learning. With direct experience in molecular testing at academic labs, at the nation's largest commercial laboratory company, and now with a leading source of specialty esoteric testing, French provides accurate and perceptive insights for laboratory leaders. It's a comprehensive look at the range of technologies and forces pushing molecular testing into the clinical market.

8:30 am–9:15 am

## Clinical Laboratories and Molecular Diagnostics: What to Expect and How Core Laboratory Services May Be Reshaped

**James Hnatyszyn, Ph.D.**, Principal Staff Scientist, Bayer Molecular Diagnostics, Berkeley, CA

As one of the world's largest companies with major interests in both pharmaceutical drugs and in vitro diagnostics (IVD), Bayer Corporation has a unique vantage point to evaluate new molecular science and develop it for clinical use. Explore this company's view of how molecular science will gain clinical acceptance, along with the changes to laboratory services that will result. It is an opportunity to explore the predictions of a major IVD company in how molecular diagnostics will change the way laboratories are organized and the services they offer.

9:15 am–10:00 am

## Molecular Diagnostics from the National Esoteric Laboratory's Perspective

**Ronald L. Weiss, M.D.**, President & COO, ARUP Laboratories, Salt Lake City, UT.

During the past two decades, national esoteric and reference testing laboratories have been first to evaluate new diagnostic technologies and bring them into the clinical market. Based on its already-considerable experience with early molecular assays, ARUP Laboratories understands the needs of hospital reference testing clients. Explore how this company expects the molecular testing market to unfold. Learn the recommendations and action steps it advises clinical laboratories take to establish and maintain a clinically and financially successful molecular testing program.

10:20 am–11:05 am

## Anatomic Pathology and Molecular Diagnostics: New Capabilities, More Integration with Clinical Labs, and Fewer Microscopes

**Paul Sohmer, M.D.**, President & CEO, TriPath Imaging, Inc., Burlington, NC.

Many experts expect that the molecular diagnostics revolution will have a far greater impact upon anatomic pathology than the clinical laboratory. That is why pathologists and their practice administrators will find this focused session to be of extraordinary interest. A three-way partnership exists between Millennium Pharmaceuticals, Becton Dickinson, and TriPath Imaging to develop molecular markers for both therapeutic and diagnostic uses. Accordingly, the perspectives presented here represent an unusual opportunity for attendees to get "behind the scenes" and hear, first-hand, how this three-partner consortium expects new molecular technologies to change the anatomic pathology profession, both short term and long term.

11:05 am–11:55 am

## Regulatory Landscape for Molecular Testing Programs

**Robert A. Gregg, Ph.D.**, Director, Regulatory Submission, Roche Diagnostics, Inc., Indianapolis, IN. For laboratories developing their own molecular testing program, this session is an invaluable source of essential information. Molecular-based laboratory tests are receiving increased attention from regulatory authorities. Compliance is a major issue today, and this session is chock full of information, insights, and analysis about how the American healthcare system and its regulatory bodies are reacting to the growing number of molecular tests, whether they are "home brew" or approved test kits.

1:00 pm–1:45 pm

## Reimbursement Issues in Molecular Diagnostics

**Lale White, CEO, XIFIN, Inc.**, San Diego, CA. Every laboratory needs to be adequately reimbursed for the molecular testing it offers clinicians. But payers are not rushing to embrace new molecular tests, nor have they proved ready to establish adequate reimbursement levels. Despite this situation, some pioneering labs are finding effective ways to work with payers to speed coverage decisions and improve reimbursement. Learn these reimbursement secrets from a company that provides billing, coding, and collection advice to laboratories nationwide. Gain an understanding of how national and regional payers are responding to claims for these new molecular tests. This information has never before been presented in a public lab industry forum.

1:45 pm–2:30 pm

## Case Study: UCLA Medical Center, Los Angeles, CA

## Integrated Health System with Academic Center

**Wayne W. Grody, M.D., Ph.D.**, Director of Molecular Pathology Laboratory.

UCLA's molecular testing activities sprang from research projects in the 1980s and has grown steadily. Like other academic centers throughout the country, its molecular testing program has been funded through a variety of methods, including grants, clinical and research studies, and reimbursement from payers. Along the way, UCLA's laboratory has learned the do's and don'ts of molecular testing. Gain valuable knowledge about the practical steps that insure success, along with the pitfalls to avoid.

2:45 pm–3:30 pm

## Case Study: Hartford Hospital, Hartford, CT

## Community Hospital with Molecular Testing Program

**Gregory Tsongalis, M.D.**, Director of Molecular Pathology.

It is still uncommon for a community hospital to develop an extensive molecular testing program. Get an inside peek into how and why this large community hospital first established a molecular testing program, one that is both clinically and financially successful. Gain essential insights about how to find sources of funding to acquire equipment and staff, as well as the best ways to evaluate the clinical value of molecular assays versus reimbursement. Learn why molecular-based testing with a community hospital can have great value in changing clinical outcomes, despite the increased costs and complexities of offering such testing.

3:30 pm–4:30 pm

## Q&A, Open Discussion With Day's Faculty

Moderated by **Cynthia K. French, Ph.D.**

Here's an unmatched opportunity! Spend a full hour with the nation's leading experts in clinical molecular diagnostics. Participate in a free-wheeling discussion about what's important, what's not, and how every laboratory should develop its unique strategy for offering molecular-based lab tests to clinicians.

4:30 pm

## Official End to the Ninth Annual Executive War College on Laboratory and Pathology Management

To register or for more information go to: [www.darkreport.com](http://www.darkreport.com) or call 888-291-2525

Every year, the *Executive War College* attracts the brightest and best laboratory managers. Why? Read below to find out...

## Ten compelling reasons why you and your lab team should be with us at the *Executive War College*!

1. 40+ presentations give you the full picture on what's really happening!
2. Get personal and up close with our experts to learn answers to your most pressing lab challenges!
3. Learn from early-adopter labs willing to tell you the truth about automation, compliance, reimbursement, and similar critical issues!
4. Update your personal network and meet experts not found at other lab gatherings!
5. Our *Executive War College* is your vital compass check—to keep your lab moving in the right direction!
6. Two days at the *Executive War College*, gives you ten times the advice, insight, and information you'd get from a lab consultant—at a fraction of the price!
7. Confidently separate fact from fiction, as working lab directors share the truth of their story and the lessons they've learned!
8. Access lab management knowledge unavailable anywhere else, at a price that averages just \$17.37 per speaker!
9. Build your knowledge base of useful ideas and industry resources necessary to keep your laboratory at the competitive edge!
10. Do all this and more, while enjoying a fine hotel and excellent food in one of America's best-loved cities!



*Compelling information to help your lab succeed!*



*Best networking in the lab industry!*

## *What they say...*

"I've enjoyed the opportunity to attend dozens of national pathology conferences. None have been more pertinent nor provided more information than the *Executive War College*."

*Tricia Hughey, Chief Operating Officer, UniPath, LLC, Denver, CO*

"The *Executive War College* gives us the inside scoop on the lab business. Everything about it gives us useful information and stimulating new ideas."

*Thomas E. Hassett, III, Group Vice President, Carolinas Medical Center, Charlotte, NC*

"The *Executive War College* is now the easy choice as THE MUST ATTEND lab conference of the year! The topics, faculty, and networking are consistently first rate."

*Dennis Hodges, Business Development, Michigan Co-Tenancy Laboratories, Ann Arbor, MI*



*Candid, truthful information about what works — and what doesn't!*

# 2004 Registration Form

Name 1	Title	Email
Name 2	Title	Email
Name 3	Title	Email
Name 4	Title	Email
Organization		
Phone	Fax	
Address		
City	State	Zip+4

Groups of 2 or more save \$50 per registration.

## TUITION DETAILS:

Seminar tuition is payable to THE DARK REPORT. Tuition includes all meeting materials, lunches and refreshments, as well as the evening receptions on Monday and Tuesday.

## TUITION CALCULATOR

<u>Executive War College (April 27-28)</u>	# people	x	\$
Register on or before March 29	_____	x \$695 = \$	_____
Register after March 29	_____	x \$755 = \$	_____
less discounts (if applicable, 2 or more)	_____	x \$ 50 = \$	_____
<u>Molecular Diagnostics for Lab Leaders (April 29)</u>			
Register on or before March 29	_____	x \$255 = \$	_____
Register after March 29	_____	x \$295 = \$	_____
TOTAL TUITION:		\$	_____

### Method of Payment:

- Check made payable to: THE DARK REPORT  
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## EARN CONTINUING EDUCATION CREDITS!

Application has been made to make continuing education units (CEUs) available through the American Association of Clinical Chemistry.

*Executive War College 2004* is managed by Stargate Events, Inc.  
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## Frequently Asked Questions about EXECUTIVE WAR COLLEGE

### When is it? Where is it?

*Executive War College 2004* takes place on Tuesday and Wednesday, April 27-28, 2004 at the Astor Crowne Plaza Hotel, New Orleans, Louisiana.

### Where can I stay?

The Astor Crown Plaza Hotel is located on Canal Street, at the corner of Bourbon Street—so it's at the hub of activities in the city and the French Quarter. As an *Executive War College 2004* attendee, your special, discounted room rate is \$169 for single occupancy (\$189 for double occupancy). To guarantee a room at these rates, please call the hotel before April 5, 2004—rooms will be released after that date. The toll-free number is 888-487-9644. Be sure to mention *Executive War College 2004* when making your reservation.

### How much does it cost?

Tuition is \$755 for *Executive War College 2004*. Attendance is optional at the one-day intensive "Molecular Diagnostics for Laboratory Leaders" (\$295 tuition) on Thursday, April 29, 2004.

### How can I save money on registration?

You have TWO ways to save money on tuition fees. If you register by March 29, your tuition is reduced to \$695. We'd also like to give your colleagues the opportunity to share the techniques and new information you'll gain there, so we're offering a \$50 discount per registration for 2 or more colleagues registering from your company or organization. (\$50 discount applies only for April 27-28 War College tuition.)

### What happens if I need to cancel?

Substitutions may be made at any time. Cancellations through April 22 will receive a full refund. Cancellations after 5:00 P.M. on April 22 are subject to a \$75 cancellation fee.

### Can I guarantee my investment?

If you aren't completely satisfied with the scope and content of *Executive War College 2004*—if you don't leave with dozens of new techniques to improve the way you do business—we'll refund your tuition in full, promptly and courteously. We're confident you'll find *Executive War College 2004* to be time and money very well spent.

### How do I register?

1. Register online at: [www.darkreport.com](http://www.darkreport.com)
2. Call 888-291-2525. Our friendly staff can register you quickly and easily, as well as answer any questions you may have.
3. Fax this complete form to 415-332-5230
4. Mail the form with payment to: THE DARK REPORT, 21806 Briarcliff Dr., Spicewood, TX 78669.

## Can I sponsor at this event?

A limited number of sponsorship and advertising opportunities remain for this event. Please contact Jalene Collins at 888-291-2525.

**Space is limited. It is essential to register early!**

**PHONE: 888-291-2525 FAX: 415-332-5230 or go to: [www.darkreport.com](http://www.darkreport.com)**

## Plus Full Day Program

**Molecular Diagnostics  
for Lab Leaders!**

(see pages 8-9)

2002 EXECUTIVE  
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On Lab and Pathology Management

# World's largest conference on laboratory and pathology management!

*Join us and get the jump  
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### Lab Industry Breakthroughs

- **50% reduction in average test TAT times in high-volume core labs**
- **"Real time" anatomic pathology through histology automation**
- **Effective cost/revenue models for clinical molecular testing programs**
- **Potent secrets of using Six Sigma and Lean in core and histology labs**
- **Marketing local pathology group subspecialty expertise nationally**
- **Using Web-based test orders and reports to build lab outreach clients**

*\*supplemented with extra learning sessions*

### Powerful Case Studies

- **Kaiser Permanente Regional Labs  
Oakland, California**
- **Fairview Health Services  
Minneapolis, Minnesota**
- **University of Miami Med Center  
Miami, Florida**
- **West Tennessee Healthcare  
Jackson, Tennessee**
- **Medical College of Virginia  
Richmond, Virginia**
- **MPL Laboratories  
Memphis, Tennessee**

*\*plus other compelling lab stories!*

### Relevant Topics

- **Molecular "make or buy" advice**
- **Digital informatics and lab data**
- **Getting paid for molecular tests**
- **Frank talk about compliance**
- **Next generation lab automation**
- **Next generation histology automation**
- **CDC's national lab quality effort**
- **Using lab test data in clinical scoring**
- **Molecular-based Pap testing**

*\*more than 40 presentations!*

### THE DARK REPORT

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2004 EXECUTIVE  
**WAR COLLEGE**  
On Lab and Pathology Management



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