

"It's the New Decade's Most Important Meeting in Lab Management..."

Will You Be There?"

MOLECULAR DIAGNOSTICS II

**Potent
& Powerful Ways to
Turbocharge
Your Lab!**

May 3-4, 2005 • Astor Crowne Plaza Hotel • New Orleans



Be first to learn from early-adopter laboratories!

- Community hospital labs now making money with molecular testing
- Automation hits histology laboratories with full force
- Quality systems are hot in healthcare! Using Six Sigma & Lean to post gains of 50% in TAT, productivity, and quality
- Secrets to getting paid for molecular lab tests
- Candid views on Medicare Anti-kickback and Stark Law Concerns
- Best ways to evaluate "make or buy" options on molecular tests
- Microarrays, ASRs, Proteomics, Genomics—learn the latest
- New winning strategies in hospital lab outreach programs

Back Again, by Demand!

Molecular Diagnostics For Laboratory Leaders II

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)

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**2005 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

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



"Updated and expanded, this year's faculty hits squarely on the two potent developments that will deeply touch every laboratory. 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.

You will also get an early and revealing look at how automation solutions provide new options in both clinical labs and histology labs. A sell-out crowd is expected, so act now to guarantee your place with us on May 3-4, 2005!

—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 2005 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.

Another new breakthrough involves major innovations generated in labs using quality management methods such as Lean and Six Sigma. They are slashing TAT by 50% and boosting 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 May 3-4 and get the knowledge and insight you need.

Best,

Robert L. Michel
War College Founder and Host

Breakthroughs in Lab Automation, POCT, LIS, Outreach, "Pay-for-Performance", Histology Automation, and More...

- How molecular technologies are acting swiftly to reshape clinical laboratory services.
- "Leadership in Lab Automation": matching the right automation and middleware solutions to your instruments.
- 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 methods to develop the right "make or buy" decision on molecular testing.
- POCT's growing role in boosting clinical outcomes is reshaping laboratory operations.

Provocative keynoters...

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

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

Join us for this exceptional Lab Summit!

Executive War College 2005 gathers the best of the best. These are among the people you'll meet and hear—sharing best practices in laboratory and pathology management:

Fredrick L. Kiechle, M.D., Ph.D., Chairman, Department of Clinical Pathology, William Beaumont Hospital

Raymond Tubbs, MD, Chairman of the Department of Clinical Pathology, Cleveland Clinic

Marilynn Bartel, Laboratory Manager, St. Francis Hospital

Dennis Padget, President, DLPadget Enterprises

Dan Jones, M.D., M.D. Anderson Cancer Center

S. Gerald Sandler M.D., Director, Transfusion Medicine, Georgetown University Hospital

Jack Shaw, Executive Director, Joint Venture Hospital Labs

Fred Meier, M.D., Division Head, System Laboratories, Henry Ford Medical Group Laboratories

James H. Godsey, Ph.D., Executive Vice President, Development, Gen Probe, Inc.

Mary Steele Williams, Director of Scientific Programs, Association of Molecular Pathology

Elaine Lyon, Ph.D., Medical Director, Molecular Genetics Section, ARUP Laboratories

Maureen Cronin, M.D., Senior Scientist, Genomic Health

Jay B. Jones, Ph.D., Director, Chemistry & Health Group Labs, Geisinger Health System

Tricia Hughey, CEO, UniPath

Richard Cooper, Attorney, McDonald Hopkins

Sunil Hazaray on "Lab-on-a-Chip" Meets Microarray: New Opportunities for These Molecular Technologies

FDA clearance for the first clinical applications of a microarray-based laboratory test is a milestone event. More microarray-based lab tests will be reaching the clinical market shortly. Here's an opportunity to explore the scope and scale of competing microarray technologies. Identify how they interact with other technologies, such as "lab-on-a-chip." Explore ways in which these technologies may support clinical breakthroughs—and require laboratories to establish their own in-house microarray capabilities.



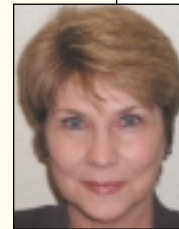
Stan Schofield of NorDx Laboratories on Building A Profitable and Thriving Hospital Outreach Program

Here's a "best-in-class" example of hospital laboratory outreach success. In the late 1990s, NorDx Laboratories affiliated with Maine Medical Center, moved into a new off-site core laboratory, and intensified its outreach sales and marketing program. Within a few years, NorDx became the dominant laboratory services provider in the Portland, Maine metro. Its rapid growth in specimens, market share, and revenue has allowed it to expand its test menu, introduce lab automation, and offer enriched laboratory information services.



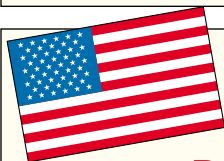
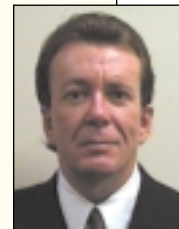
Joyce Santis of Sonora Quest Laboratories on the "Case for Quality" in Hospital/Commercial Lab Joint Venture

In Arizona, Sonora Quest Laboratories (SQL) is the only healthcare provider to have ever been honored with that state's "Pioneer Award" for quality. A joint venture laboratory owned by Banner Health and Quest Diagnostics Incorporated, Sonora Quest Laboratories may be the nation's best example of using quality management systems like Six Sigma to continuously improve every aspect of lab operations. You will hear how SQL measures every aspect of its performance. By driving the quality of lab testing and lab services to higher levels than competing laboratories, SQL has gained a dominant share of the Arizona market.

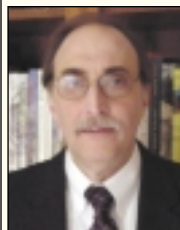
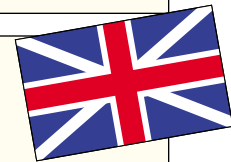


John McCarty on LabOne, Inc. & Health Alliance: Supporting Growth and Profitability in a Dual Environment

There's two stories to be heard in this case study. Over the past decade, LabOne has grown to become the third-largest independent commercial lab company in the United States. In early 2004, it acquired the laboratory assets of Health Alliance of Cincinnati and became the contract manager for Health Alliance's hospital laboratories. This *War College* exclusive is the first public presentation where LabOne shares the business strategies which fuel its sustained, multi-year growth and reveals the details of its Cincinnati laboratory operations. Learn which management initiatives introduced by LabOne brought the greatest benefit to the Health Alliance hospital laboratories.



U.S.A versus U.K.: Who Runs Better Laboratories?



Don Landek

Who's better at running laboratories, the U.K. or the U.S.A? Join us for a historic first: a detailed, side-by-side look at a laboratory in the United Kingdom and a laboratory in the United States. We match Landek's University Hospital Health System of Cleveland, Ohio against Ricketts' North Middlesex University Hospital of London, England. You'll be surprised at the differences—and the similarities! Compare costs, labor productivity, and how automation solutions are used in each country. Gain new ideas you can take back to your own laboratory.

David Ricketts



Monday, May 2

4:00 PM-6:00 PM

Special Sessions by Invitation

Abbott Laboratories
Atlas Medical
Bayer Diagnostics
Dade Behring
Ortho-Clinical Diagnostics

6:30 PM-8:30 PM

Early Registration

Get Acquainted Reception with Refreshments

Tuesday, May 3

8:15 AM-9:00 AM

Announcing Laboratory Medicine's Golden Age: Lean, Molecular, and Patient Safety Boost the Value of Laboratory Testing to Healthcare

Robert L. Michel, Editor-in-Chief, THE DARK REPORT, Spicewood, TX

It may be the "perfect storm" which favors laboratory medicine. Lean quality management methods are transforming laboratory operations. With each passing month, more new molecular assays reach the clinical marketplace. Patient safety initiatives—and the need for clinicians to improve outcomes—motivate physicians to more effectively use laboratory tests. Learn how these three powerful trends intersect in a way that positions laboratory medicine to make its highest-ever added-value contribution to clinicians.

9:00 AM-9:45 AM

Case Study: NorDx Laboratories, Scarborough, ME

Hospital Outreach Program Builds Dominant Market Share

Stan Schofield, President

(See description on page 3.)

10:15 AM-11:05 AM

Case Study: Sonora Quest Laboratories, Tempe, AZ

Hospital-Commercial Lab Joint Venture Goes "High Performance"

Joyce Santis, COO

(See description on page 3.)

11:05 AM-11:55 AM

Case Study: LabOne, Inc., Lenexa, KS, and Health Alliance, Cincinnati, OH Multi-Hospital/Commercial Lab Joint Venture

John McCarty, CFO and Mike Asselta, COO,

LabOne; Ron Long, CFO, Health Alliance

(See description on page 3.)

1:00 PM-1:50 PM

Case Study: Fleury Diagnostics, Sao Paulo, Brazil

Ewaldo Russo, M.D., Ph.D., CEO; Rogerio Rabelo, M.D., Ph.D., Product Manager, Core Lab & POCT
Consumer-directed healthcare is a new phenome-

non in the United States. Not so in Brazil, where individuals either pay directly for their healthcare or utilize private health insurance. Because Brazilian patients have choice, Fleury Diagnostics developed enriched services to distinguish itself to patients and referring physicians as the "Lexus of Laboratories" in Brazil. Its largest patient service center (PSC) not only collects blood from as many as 2,500 patients per day, but that same PSC offers full diagnostic services in radiology, nuclear medicine, endoscopy, bronchoscopy, colposcopy, and hysteroscopy. Fleury's patients strongly approve the concept of the "one stop diagnostic shop" with humanized, patient-focused service. Fleury has plenty of fascinating lessons to share about how a laboratory can meet and exceed the expectations of consumers who can steer their laboratory testing business to any number of competing laboratories.

2:00 PM-2:50 PM

Concurrent Breakout Sessions 1

Powerful Methods to Maximize Pathologist Productivity and Compensation

Dennis Padget, President, DLPadget Enterprises, Inc., Simpsonville, KY

Anatomic pathologists face growing pressure to increase their individual productivity. At the same time, payers are decreasing reimbursement. With less money to go around, many pathology group practices are introducing compensation programs linked to pathologist-productivity. In this candid presentation, one of the nation's leading experts in pathology practice management describes different pathology compensation models. His counsel is that linking pathologist productivity to compensation in many private practice settings may trigger more pitfalls than profits.

Building a Financially-Sustainable Molecular Diagnostics Program

Fredrick L. Kiechle, M.D., Ph.D., Chairman, Department of Clinical Pathology, William Beaumont Hospital, Royal Oak, MI

For most hospital laboratories, molecular diagnostic testing is a budget-busting black hole. At the Beaumont Health System, molecular testing has grown steadily in recent years. This lab has learned essential lessons: how to determine when the time is right to set up molecular tests internally, how to negotiate effective contracts with molecular vendors, and why clinician education is necessary to insure that new molecular test introductions are clinically successful and financially-viable.

How PathNET's Single-View Lab Resulting System Puts Labs in the Information Technology "Driver's Seat"

Lindsay Allan, General Manager, PathNET Services, Burnaby, BC, Canada

It was an unlikely collaboration between two intense laboratory competitors. PathNet Services is jointly-owned and was created by BC Biomedical Laboratories and MDS Metro Laboratories, both based in British Columbia. When a physician opens

the PathNet Web browser window, he/she can access all the test results for his/her patient, regardless of whether BC Biomed or MDS Metro performed the test. LOINC (Logical Observation Identifiers Names and Codes) is used to link the two laboratory test data repositories. Since its launch, PathNET now is a portal for Pharmanet, the British Columbia repository of patients' drug histories. Emergency rooms, pharmacies, and selected physician groups use PathNet to access the Pharmanet information. As a result of this IT collaboration between competing laboratories, their PathNet system is positioned to be a major information conduit for other sectors of the British Columbia healthcare system.

"Leadership in Laboratory Automation": Using Automation Solutions to Get the Highest Performance from Existing Lab Layouts

Kris Bailey, Managing Director, AICON Diagnostics, Kitchener, Ontario, Canada

Laboratory automation is a controversial topic. That's because few laboratories in the United States have done a superlative job with the lab automation solutions introduced into their laboratory. One major reason is that a laboratory will select automation solutions and middleware that doesn't work well with some of its existing analyzers. Another situation involves laboratories which installed pieces of automation and now want to link those existing automated islands with TLA (total laboratory automation). This presentation offers forthright and unique answers to many of the often-misunderstood problems caused by the wrong automation decisions. It provides specific techniques that lab managers can use to properly match automation opportunities within their laboratory to the most effective automation and middleware solutions.

3:00 PM-3:50 PM

Concurrent Breakout Sessions 2

How POCT & Standardized Lab Testing Feeds Geisinger's Molecular and Outcomes Efforts

Jay B. Jones, Ph.D., Director, Chemistry & Health Group Labs, Geisinger Health System, Danville, PA

This is more than a success story about point-of-care testing (POCT). It shows how POCT can play an integral role in boosting clinical outcomes. POCT within Geisinger's hospitals, clinics, and physician offices has always been extensive. Since 1999, standardized test codes and test methodologies have been used in all lab testing. POCT was linked across the system and POCT results are captured in both the LIS and Geisinger's electronic medical record (EMR). In recent years, Geisinger's newly-formed Outcomes Institute has begun building a bio-repository. Utilizing its information-rich lab test data platform and the five years of patient data in its EMR, Geisinger is now data mining for patterns involved in such diseases as osteoporosis, schizophrenia, and obesity. It is also one of seven sites nationally currently feeding data into the Centers for Medicare and Medicaid Services' (CMS) "Pay for Performance" program.



Pathology Professional Services: How to Negotiate to Best Advantage with Managed Care Companies

Jack Shaw, Executive Director, Joint Venture Hospital Labs

Coming Soon to Your Lab: National Quality Indicators for Laboratory Testing

Fred Meier, M.D., Division Head, System Laboratories, Henry Ford Medical Group Laboratories, Detroit, MI

It's a lab industry first! Just four days after the Institute for Quality in Laboratory Medicine (IQLM) publicly announces its national indicators to measure the quality of laboratory testing services, *War College* attendees will get a detailed briefing on the specific indicators and how they will be measured. Dr. Meier participated on the IQLM team that developed these indicators. It's an opportunity to learn, first-hand, how and why these national laboratory quality indicators will be used to improve the performance of the nation's laboratories.

When Specialty Physicians Want a Share of Anatomic Pathology Fees: Legal Issues Every Laboratory Must Know

Thomas A. Bartrum, Esq., Waller Lansden Dortch & Davis, Nashville, TN

Anatomic pathology (AP) laboratory condominiums are just one dimension of a major threat to pathology. Growing numbers of specialist physician groups are asking their local pathologists to share either or both the AP technical and professional fees, using a variety of contractual arrangements. At the same time, the Office of the Inspector General (OIG) is sending plenty of signals that it considers any situation where a referring physician "profits" from an ancillary service referral to be troublesome. Bartrum's recent interaction with the OIG on its Advisory Opinion 04-17 gives him unique insights. This session is a "must attend" for every pathology group facing requests from referring physicians to share in AP technical and/or professional fees.

4:00 PM-4:50 PM Concurrent Breakout Sessions 3

Building Profitable Shared Pathology Technical Laboratories: the Connecticut Experience

Robert Tessier, President, HBP Services, Inc., Fort Lee, NJ

Local pathology groups in Connecticut, recognizing the threat from national laboratories, formed a joint venture to build and operate a pathology laboratory. Five pathology groups and six hospitals now own this joint venture cytology laboratory. The operational and financial per-

formance of this shared lab was substantial enough to cause two more hospitals to shut down their cytology labs and refer their specimens to the shared cytology laboratory. Now some participants in the shared cytology laboratory are planning to build and operate a regional esoteric pathology laboratory. It's a compelling story about how local pathologists recognized the increased marketplace competition for pathology specimens and took initiative to protect their turf—while expanding their access to new sources of specimens and revenue.

No STAT Testing at Oklahoma University Medical Center! Workflow Redesign Boosts Lab's Performance

Ken Blick, Ph.D., Director of Clinical Chemistry and Information Systems, Oklahoma University Health Sciences Center (OUHSC), Oklahoma City, OK

Remarkably, this academic center laboratory has totally eliminated STAT testing. At OUHSC, laboratory administration identified outliers in a variety of performance measurements. It also studied what caused delays between the lab test order and receipt of results by the referring physician. It then applied a variety of management tools to re-engineer work flow at the pre-analytical, analytical, and post-analytical stages, including single piece work flow. Now average test turnaround times are consistent—and fast! Not only has STAT testing been eliminated in the hospital, but physicians now have confidence in the lab's ability to deliver a quality test result every time. This has decreased utilization by reducing the number of "rule out" tests ordered by physicians to confirm that the first set of lab test results were reliable.

How Molecular Testing Supports Oncology at M.D. Anderson Cancer Center

Dan Jones, M.D., Ph.D., Director, Molecular Diagnostics Laboratory, M.D. Anderson Cancer Center, Houston, TX

Within the United States, M.D. Anderson Cancer Center holds a unique distinction. At 475 beds, it is the largest acute care hospital devoted exclusively to cancer. To support this clinical mission, its laboratory and anatomic pathologists are organized in distinctly different ways from other hospitals. This laboratory is also an early-adopter of molecular diagnostic tests. Because oncology is widely-predicted to be one of laboratory medicine's fastest-growing areas, the M.D. Anderson Cancer Center laboratory provides an early look at how molecular diagnostics stimulates changes to how labs support clinicians in early detection, diagnosis, prognosis, and monitoring of cancer patients.

Why SISH, And FISH, Are Coming to Your Lab at Light Speed

Raymond R. Tubbs, M.D., Chairman of the

Department of Clinical Pathology, Cleveland Clinic, Cleveland, OH

A "comer" in the anatomic pathology profession is SISH (silver in situ hybridization). It offers several benefits over FISH (fluorescence in situ hybridization). Because FISH requires expensive equipment and is a complex procedure, only a limited number of laboratories have set up the test. In contrast, SISH utilizes a non-fluorescent tag, allowing the slide to be read utilizing a bright field microscope (the same microscope used by pathologists to diagnose over 95% of cancers and infectious diseases in histology today). SISH technology produces a clean, gene-based signal without the complexity of FISH. Experts believe SISH has the potential to become a mainstream methodology. If so, this will be of major interest to laboratory administrators and pathologists. Explore how this technology was developed and how it is changing pathology practice patterns at the Cleveland Clinic.

5:00 PM-5:40 PM

Panel: Discerning Molecular Diagnostic's Impact on Lab Operations, Information Technologies, and Clinical Outcomes

Moderator: Robert L. Michel; Panel: Fred Meier, M.D., Fredrick Kiechle, M.D., Ph.D., Stan Schofield, Jay Jones, Ph.D

This panel discussion is always free-wheeling and often spicy. These keen thinkers offer insights about how molecular technologies will transform different aspects of clinical laboratories and anatomic pathology. The goal is to identify and describe the new types of operational models and information technology capabilities that will be required if laboratories are to successfully respond to the impact of genetic and molecular technologies.

5:45 PM-7:45 PM

Grand Reception

Wednesday, May 4

8:00 AM–8:40 AM

Genetic Medicine's Information Overload and How Information Technology Must Support Physicians' Diagnoses

Kareem Saad, Worldwide Genomics Leader, IBM Healthcare Division, Armonk, NY

It's a unique opportunity to hear the grand vision for how clinicians will have an integrated informatics capability for "on-demand" diagnosis and treatment. This information technology giant is developing middleware solutions to meld laboratory test results with databases for patient medical history, genetic information, imaging, prescription drug data, and clinical treatment pathways. The goal is to instantly match a patient's clinical situation with the knowledge in multiple repositories, then guide the physician to the right response. One consequence of such a master solution is the need for faster turnaround time on laboratory results to meet the "real-time" use of that data by clinicians.

8:40 AM–9:25 AM

Lab-On-A-Chip Meets Microarray: New Opportunities for These Molecular Technologies

Sunil Hazaray, Vice President, Roche Molecular Diagnostics, Indianapolis, IN
(See Description on Page 3.)

9:25 AM–10:05 AM

Potent Lessons in How Lean Management Methods Turbocharge Lab Operations

Mark Jamrog, President & CEO, SMC Management Group, Inc., Edwardsburg, MI
Learn the latest about Lean successes in laboratories. Lean expert Mark Jamrog has helped such healthcare giants as Johnson & Johnson Co. implement Lean quality management methods throughout their companies. During the past 36 months, he guided several of the nation's best-known health system laboratories as they implement Lean make-overs in their high-volume core chemistry and hematology labs. Now you can learn how these early adopter labs, in 12- to 16-week Lean projects, reduced average test turnaround times by 50%, boosted med tech productivity by 40%, slashed unnecessary costs, and increased the quality of lab testing services.

10:25 AM–11:05 AM

Why "Pay-for-Performance" Programs Are Multiplying in Medicare and the Private Sector

Beatriz Garcia Stamps, M.D., Medical Director, Arizona Medical Board, Scottsdale, AZ
This long-standing prediction of THE DARK REPORT is now coming true. Each month, a new "pay-for-performance" initiative pops up somewhere in the United States. Earlier this year,

Medicare announced a demonstration pay-for-performance project involving ten medical clinics and the ability of their physicians to improve outcomes in exchange for additional reimbursement. Explore why payers are funding these programs. Learn how they work and what types of clinical gains are measured and rewarded. Hospitals and physicians have been first to participate, but laboratories and pathologists will soon have their own pay-for-performance opportunities.

11:05 AM–11:50 AM

International Case Study: University Hospital Health System, Cleveland, OH and North Middlesex University Hospital, London, England

David Ricketts, Laboratory Manager, NMUH and Don Landek, Director of Laboratories, UHHC
(See Description on Page 3.)

1:00 PM–1:50 PM

Breakout Sessions 4

RFID versus Bar Code: First Laboratory Use at Georgetown University Hospital's Blood Bank

S. Gerald Sandler M.D., Director, Transfusion Medicine, Georgetown University Hospital, Washington, DC

Georgetown University Hospital's blood bank is launching a trial project to evaluate the use of RFID (radio frequency identification) devices for clinical applications. RFID tags will be attached to blood unit bags prior to collection. RFID will then be used to track the blood units from point of collection at the donor center through point of transfusion within the hospital. RFID tags have advantages over bar codes. RFID tags can be read as long as they are within range of the reader. In contrast, bar codes are line-of-sight technology, which means the scanner must be physically oriented to the bar code to read it. As the cost of RFID tags drops, it is expected that RFID will eventually become the technology of choice for patient identification, tagging therapeutic drugs, and tracking laboratory specimens.

Forging a Regional Pathology Powerhouse: Beating National Labs with the Molecular Advantage

Tricia Hughey, CEO, UniPath, LLC, Denver, CO
UniPath's 25 pathologists serve eight hospitals in Greater Denver. Recognizing the competitive threat from national laboratories in both anatomic pathology and clinical laboratory services, this pathology super-group is responding with several business strategies. A growing molecular diagnostics test menu anchors its competitive response. Performed locally, UniPath offers faster turnaround times on molecular tests and allows referring clinicians to have easy and regular access to UniPath's pathologists. UniPath is marketing these enhanced molecular testing

services in tandem with a local hospital outreach program. Find out how this proactive mix of enriched testing and sales and marketing is helping UniPath capture greater volumes of specimens and revenues.

Six Evolving "Hot Button" Legal Issues That Every Clinical Lab and Pathology Group Should Watch

Richard S. Cooper, Esq., Partner, McDonald, Hopkins, Cleveland, OH

During the past year, a number of developments in law and compliance have added new risks. This presentation offers sophisticated and nuanced information about six "hot button" issues that need recognition and response by laboratories and pathology group practices. These issues range from legislative restrictions impacting account billing and payer/pathologist battles over professional component billing to negotiating out-of-network waivers and developments in reassignment rules that create new opportunities for labs and pathologists.

Automating the Histology Laboratory: Invaluable Lessons from an Early Adopter

Mehrdad Nadji, M.D., Professor of Pathology, University of Miami School of Medicine/Jackson Memorial Hospital, Miami, FL

Using new technology that automates several aspects of the histology laboratory, Dr. Nadji and his colleagues have 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 recently 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 provide diagnoses to 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 histology and anatomic pathology.

2:00 PM–2:50 PM

Breakout Sessions 5

Eliminating the LIS: How the Hospital-wide Electronic Medical Record (EMR) Changes Laboratory Information Systems

Marilynn Bartel, Laboratory Manager, St. Francis Hospital, Tulsa, OK

When St. Francis Hospital installed a universal electronic medical record system (EMR) three years ago, it caused major changes to how its laboratory captured laboratory test results and fed that information into the clinical data repository. Today, the laboratory operates without a traditional laboratory information system (LIS). Instead, lab instruments feed test results into



middleware software modules. These middleware solutions then deliver laboratory test results directly into the health system's EMR repository. They also send lab test results directly to lab outreach clients. Operating without an LIS generates cost savings in several surprising ways. It also alters how the laboratory selects and installs new diagnostic testing instruments. Attend this session and peek into the future of the "LIS-less" laboratory.

How Medtox Uses Lean to Drive Major Gains in Pre-Analytical and Analytical Processes

Kevin Wiersma, Chief Operating Officer, MedTox, Inc., St. Paul, MN

MedTox may have been the first laboratory to fully embrace Lean quality management techniques. Its initial project, completed two years ago, was a make-over of its pre-analytical work processes. Impressed by how Lean methods leveled workflow, improved quality, and boosted productivity, MedTox then moved Lean into other departments. Lean projects streamlined work processes on both its forensic toxicology laboratory and clinical laboratory. Current Lean projects target the sales and marketing process. Be first to learn how Lean techniques are improving the performance of the MedTox sales team.

Microarrays and Their Future in Clinical Diagnostics: Everything You Wanted to Know

Graham Lidgard, Ph.D., Senior Vice President, Research & Development, Nanogen, Inc., San Diego, CA

Here's an overview of microarrays and how they are expected to transform clinical practices. Explore the different applications for competing microarray technologies. Identify which microarray products are likely to find swift acceptance in the microarray marketplace and what essential steps every laboratory should take to make the right decisions about acquiring and offering microarray-based diagnostic tests

"Lean" Touchdowns at Harrison Hospital Laboratories

Lloyd Castillo, Director of Laboratory, Harrison Hospital, Bremerton, WA

When this hospital laboratory found itself unable to recruit adequate numbers of lab staff, it turned to Six Sigma to re-engineer work processes in the lab. The goal was to improve productivity and reduce stress and overtime for existing staff. Without consultants, but with the support of an instrument vendor, the laboratory's Six Sigma initiative generated dramatic increases in laboratory productivity while reducing errors. The number of times tubes were handled was significantly reduced, as was lab staff overtime and

stress. Get the inside story on how home-grown Six Sigma projects can help labs resolve a host of operational challenges.

3:00 PM-3:30 PM

Key Learnings from War College Faculty that Can Make Your Lab a Winner

Robert Michel, Editor-in-Chief, THE DARK REPORT, Spicewood, TX

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 Executive War College 2005.

3:30 PM

EXECUTIVE WAR COLLEGE Ends



Optional Full Day Program on Thursday, May 5

Molecular Diagnostics for Laboratory Leaders II!

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

**Everything
Molecular!
For all
Labs!**

**Last Year's Success Is Back!
More Topics!
Essential Insights!**

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

You see it everywhere in your healthcare community. Growing numbers of clinicians now use molecular diagnostic tests in their medical practice. Savvy consumers are quickly finding—and demanding molecular tests!

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. Our experts will guide you through the essentials of molecular diagnostics in oncology, genetics, infectious disease, and pharmacogenomics. You'll get all the info you need to help craft a winning molecular strategy for your laboratory and pathology practice.

This is an essential one-day session you can't afford to miss! 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!

Revealing Sessions on...

- Molecular in oncology
- Molecular in genetics
- Molecular in infectious disease
- Molecular in pharmacogenomics
- Reimbursement secrets to get paid for molecular tests
- Must-know legal issues
- Lab informatics challenges created by molecular test programs
- Network with nation's premier molecular diagnostic experts

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FOR EARLY-BIRD SAVINGS!**





Agenda

▶ register separately for Thursday, May 5 • 8:00 a.m – 4:30 p.m.

Molecular Diagnostics for Laboratory Leaders II

8:00 AM–4:30 PM

Preparing for Clinical Use of Molecular Diagnostics

Cynthia K. French, Ph.D., Vice President & Chief Science Officer; Specialty Laboratories, Inc., Valencia, CA

Molecular diagnostics is rapidly moving out of research and academic center laboratories and into community hospital labs. Here's a concise look at the main drivers behind clinical acceptance of molecular diagnostic tests. It provides the understanding necessary to link the day's presentations to follow on this exceptional overview of the molecular diagnostics marketplace.

8:30 AM–9:10 AM

Molecular Diagnostics in Oncology

Maureen Cronin, Ph.D., Vice President, Technology Development, Genomic Health, Inc., Redwood City, CA

Oncology is expected to be the medical specialty where molecular diagnostics will have the greatest impact. Already a growing menu of molecular assays helps clinicians diagnose cancer earlier and guides them to understand which therapies will be most effective against a patient's specific type of cancer. Learn about the range of molecular technologies now utilized by oncologists. Understand which types of cancers will be most affected by new advances in molecular diagnostics.

9:10 AM–9:50 AM

Genetic Molecular Tests Support a Growing Number of Medical Specialties

Elaine Lyon, Ph.D., Medical Director, Molecular Genetics Section of the Molecular Pathology Laboratory, ARUP Laboratories, Inc., Salt Lake City, UT

"Genetic testing" is already used by several medical specialties. Until recently, a large number of these assays were generally ordered by genetists. But that is changing rapidly as more clinicians directly order genetic tests. At the same time, improved diagnostic technologies make it simpler and easier for community hospital labs to set up and perform such genetic tests as cystic fibrosis (CF) and Factor V Leiden. No longer are genetists the primary source of lab test orders. Gain a perspective on the range of genetic testing and which genetic technologies are expected to have the greatest clinical impact during the next few years.

10:10 AM–10:50 AM

Molecular Diagnostics in Infectious Disease

James H. Godsey, Ph.D., Executive Vice President, Development, Gen Probe, Inc., San Diego, CA

Widespread clinical acceptance of molecular testing for HIV and HCV has opened doors for other applications of molecular technologies in infectious disease testing. This presentation will cover the range of molecular technologies finding applications in infectious disease testing. It will identify molecular technologies most likely to be effective in infectious disease testing.

10:50 AM–11:30 AM

Molecular Diagnostics in Pharmacogenomics

Gwen McMillin, Ph.D., Medical Director of the Clinical Toxicology and Trace Elements Laboratories, ARUP Laboratories, Inc., Salt Lake City, UT

Pharmacogenomics will be an explosive growth area for molecular diagnostics. Psychiatry is the cutting edge of this field, using pre-therapeutic molecular testing to evaluate a patient's potential for therapeutic value and the risk of adverse events. Oncology is another field where molecular testing is expanding rapidly, particularly in the use of such tests to help with pain management. Consumer demand will be a major driver in accelerating the use of pharmacogenomics in clinical settings.

11:30 AM–12:10 PM

How to Identify the Next Test out of the Molecular Technology Chute: Which Developing Assays to Watch

Mary Steele Williams, Director of Scientific Programs, Association of Molecular Pathology, Bethesda, MD

Limited laboratory budgets make it imperative that lab administrators and pathologists add new molecular tests only at the time when physician use of the tests is established and payers cover and adequately reimburse for these new assays. The Association of Molecular Pathology (AMP) has closely tracked the growth of molecular diagnostics in recent years. Here's a real-world look at what factors contribute to the widespread clinical and payer acceptance of specific new molecular assays. Using recent examples, it provides useful guidance to help hospital laboratories accurately gauge the right time to offer new molecular assays to their referring physicians.

1:10 PM–1:50 PM

Legal Issues in Molecular Diagnostics—From Intellectual Property Concerns to Regulatory Issues

Grant Bagley, Esq., Partner, Arnold & Porter LLP, Washington, DC

Genetic medicine triggers a host of new legal issues that affect laboratory testing services. As molecular testing finds its way into more hospital laboratories and pathology group practices, these molecular

tests bring a unique set of legal problems. Identify key legal concepts and regulatory concerns that must be addressed by any laboratory offering laboratory tests based on molecular technologies.

1:50 PM–2:30 PM

Reimbursement Issues in Molecular Diagnostics

Virginia Tobiason, Director of Corporate Reimbursement & Health Policy, Abbott Laboratories, Abbott Park, IL

All laboratories require adequate reimbursement for assays utilizing molecular technologies. One of the nation's leading experts on reimbursement for molecular diagnostics shares her insights and experience about how and why Medicare and private payers make coverage decisions and establish reimbursement levels. Discover essential steps your laboratory can take to successfully negotiate the reimbursement maze for your molecular testing menu.

2:45 PM–3:30 PM

Genetic Data in the LIS and EMR

Michael Feldman, M.D., Ph.D., Assistant Professor of Pathology and Assistant Dean for IT Academic Programs, University of Pennsylvania Health System, Philadelphia, PA and Mark Hoffman, Ph.D., Solution Manager, Cerner Corporation, Kansas City, MO

One prediction about molecular diagnostics is that it will exponentially increase the volume of data laboratories must capture, store, analyze, and make available to clinicians. Get an early peek into how one prominent laboratory and a major healthcare IT vendor are responding to the increased IT demands of molecular diagnostics. Identify the types of challenges created by a growing molecular testing program. Learn which solutions show the best promise at this time.

3:30 PM–4:30 PM

Q&A and Open Discussion With Day's Faculty

Moderated by Cynthia K. French, Ph.D.

Take this exceptional opportunity to spend a full hour with the nation's leading experts in clinical molecular diagnostics! Listen to the range of opinion and insight on issues critical to the success of a molecular diagnostics program.

4:30 PM

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

To register or for more information go to: 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...

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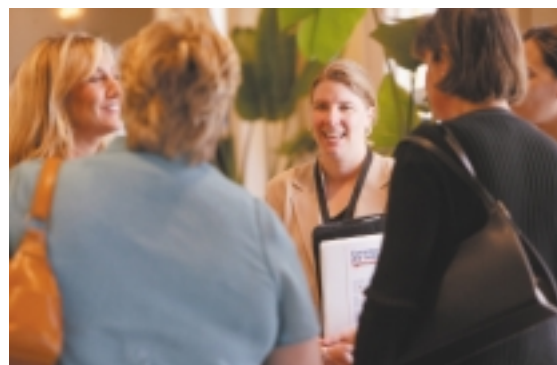
Gary Assarian, M.D., Medical Director, Joint Venture Hospital Laboratory Network, Detroit, MI

"I feel attendance at the annual *Executive War College* is mandatory. There just isn't an option. The *War College* showcases laboratory leaders who have innovative thinking and offer ways to quickly implement market-leading ideas."

Jim Zache, Director of Sales & Marketing, Medical Science Labs, Wauwatosa, WI

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



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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

<i>Executive War College (May 3-4)</i>	# people	x	\$
Register on or before March 21	_____	x \$695 = \$	_____
Register after March 21	_____	x \$770 = \$	_____
less discounts (if applicable, 2 or more)	_____	x \$ 50 = \$	_____
<i>Molecular Diagnostics for Lab Leaders (May 5)</i>	# people	x	\$
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Application has been made to make continuing education units (CEUs) available through the American Association of Clinical Chemistry.

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Frequently Asked Questions about EXECUTIVE WAR COLLEGE

When is it? Where is it?

Executive War College 2005 takes place on Tuesday and Wednesday, May 3-4, 2005 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 2005* attendee, your special, discounted room rate is \$165 for single occupancy (\$175 for double occupancy). To guarantee a room at these rates, please call the hotel before April 11, 2005—rooms will be released after that date. The toll-free number is 888-487-9644. Be sure to mention *Executive War College 2005* when making your reservation.

How much does it cost?

Tuition is \$770 for *Executive War College 2005*. Attendance is optional at the one-day intensive "Molecular Diagnostics for Laboratory Leaders II" (\$310 tuition) on Thursday, May 5, 2005.

How can I save money on registration?

You have TWO ways to save money on tuition fees. If you register by March 21, 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 May 3-4 *War College* tuition.)

What happens if I need to cancel?

Substitutions may be made at any time. Cancellations through April 18 will receive a full refund. Cancellations after 5:00 P.M. on April 18 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 2005*—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 2005* to be time and money very well spent.

How do I register?

1. Register online at: 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 415-331-3623
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!

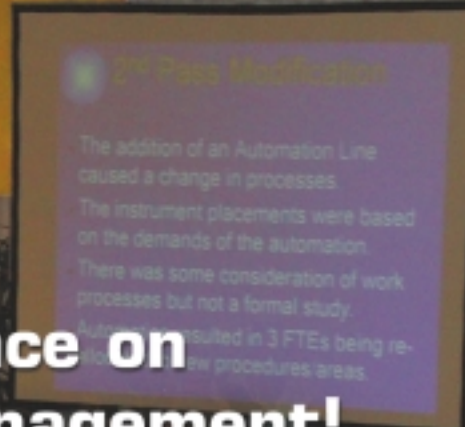
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Molecular Diagnostics for Lab Leaders II!

(see pages 8-9)

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- University Hospital Health System Labs, Cleveland, Ohio
- North Middlesex University Hospital Labs, Middlesex, England
- Sonora Quest Laboratories, Tempe, Arizona
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- Digital informatics and lab data
- Getting paid for molecular tests
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*more than 40 presentations!

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