

*From the Desk of R. Lewis Dark...*

# THE **RED** DARK **REPORT**

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

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**R. Lewis Dark**

Founder & Publisher



## ***More Consolidation: Where Will It Lead?***

I CERTAINLY DID NOT FORESEE ALL THE LAB ACQUISITION ACTIVITY that occurred during 2002. Compared to recent years, both **Quest Diagnostics Incorporated** and **Laboratory Corporation of America** have been on a buying spree this year.

Quest Diagnostics acquired **American Medical Laboratories** in April and has an agreement to acquire **Unilab Corporation**, pending a decision by the Federal Trade Commission. LabCorp bought **Dynacare** and has now signed an agreement to acquire **DIANON Systems**, subject to shareholder approvals and regulatory reviews. There have also been several acquisitions of smaller, private labs throughout 2002.

In simplest terms, it means the biggest labs are getting bigger and the smaller labs are shrinking in number. In May, THE DARK REPORT wrote about how the two blood brothers now hold a national oligopoly in the physicians' office segment, along with regional monopolies in selected cities throughout the United States. (*See TDR, May 13, 2002.*) How this will affect the marketplace for laboratory testing services has yet to be seen.

As I survey the nation's healthcare system, I think the clinical laboratory industry may be the first clinical segment to have such a dominant oligopoly at the national level. By my guess, combined, LabCorp and Quest Diagnostics control upwards of 70% of the national market for lab specimens originating in physicians' offices. By comparison, in the hospital segment, **HCA** and **Tenet Healthcare**, combined, only own about 9% of the nations' hospitals.

Anatomic pathology may be next in line to undergo extensive consolidation. LabCorp's purchase of DIANON is a direct statement that it intends to compete more aggressively for tissue specimens that originate in physicians' offices. This has traditionally been a captive market for local anatomic pathology group practices. Meanwhile, **AmeriPath** has quietly continued to scoop up three to six pathology practices each year. It now employs 400 pathologists. Local pathology groups that fail to respond to this marketplace trend may find themselves extinct because of their failure to adapt to a changing environment.

All of this consolidation activity raises a critical business question: is the competitive marketplace now tilted in favor of larger labs, with their economies of scale? There are examples of regional labs and pathology "super-groups" which are doing well. But can they sustain this success against competition from our industry's ever-growing billion-dollar oligarchs? **TDR**

# Another Lab Acquisition: LabCorp To Buy DIANON

*In purchasing DIANON, LabCorp signals its interest in building anatomic path revenue*

**CEO SUMMARY:** *Laboratory Corporation of America Holdings will pay almost \$598 million to buy DIANON Systems, Inc. of Stratford, Connecticut. With this move, anatomic pathology becomes a high profile growth target for LabCorp. During the past eight years, DIANON Systems has built a national business providing highly specialized anatomic pathology and esoteric testing services to office-based physicians.*

IT'S ANOTHER SIGN of the swift changes now transforming the profession of anatomic pathology.

**Laboratory Corporation of America Holdings** announced an agreement to acquire **DIANON Systems, Inc.** on November 11, 2002. In an all-cash offer (which includes using approximately \$50 million in DIANON cash), LabCorp will pay approximately \$598 million, or \$47.50 per share. This is an 18% premium over DIANON's closing stock price of \$40.19 on November 8.

The transaction must be approved by DIANON's shareholders and pass review by regulators. Both companies believe the approvals will be obtained and the acquisition can be completed by the end of March 2002.

This sizeable investment reflects LabCorp's commitment to expanding its activities in the market for specialized anatomic pathology and esoteric testing services. LabCorp's Chairman and CEO, Thomas P. Mac Mahon, described the value he believes will come from combining the resources of LabCorp and DIANON.

"DIANON Systems is a company I've admired for many years," stated Mac Mahon. "It fits extremely well with our strategic direction at LabCorp because of its established role in cancer diagnostics.

"Specifically, we believe that, in the next two to five years, new technologies in testing for cancer will profoundly change the way patients are

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diagnosed and treated for cancer,” he explained. “DIANON fulfills our dream of having a company within the LabCorp family that is totally devoted to cancer. It complements our diligent efforts to execute relationships involving oncology-based testing with strategic partners such as **Correlogic Systems, Celera Diagnostics, EXACT Sciences, and Myriad Genetics.**”

### **DIANON To Retain Identity**

At this time, LabCorp intends to operate DIANON Systems under its existing name and as a separate marketing vehicle. “The opportunity is to combine LabCorp’s skills with those of DIANON’s in the outpatient market for oncology services,” noted Mac Mahon.

“In particular, we plan on taking DIANON’s best practices with its CarePath™ information product and its top-performing sales system and matching them with LabCorp’s distribution channels,” he added. “LabCorp’s access through managed care contracts can generate additional specimens for DIANON. At the same time, DIANON’s coverage in certain regions around the country opens new opportunities for other lines of testing offered by LabCorp.”

### **Business Model**

The business model LabCorp intends to use in developing DIANON will be based on its Center for Molecular Biology and Pathology (CMBP) in Research Triangle Park, North Carolina. “During the past 13 years, we’ve used the CMBP business model to evaluate and introduce new diagnostics technologies in infectious diseases,” stated Bradford T. Smith, Executive Vice President at LabCorp. “Throughout the last decade, this business model has helped us become an early leader in such areas as HIV and Hepatitis C testing.”

LabCorp hopes to duplicate CMBP’s clinical success in infectious disease. It believes oncology is becoming one of the biggest growth opportunities in diagnostic testing. LabCorp plans to build a specialty oncology business around DIANON.

“Two things will drive the cancer market,” predicted Smith. First, researchers are using the human genome map to develop ways to assess a patient’s risk to disease and the predisposition they may have to specific diseases. Much of this new research is aimed at cancer and will lead to a growing number of better tests for detecting and assessing different types of cancer.

### **Cancer Diagnostics**

“Second, population demographics predict a growing number of cancer cases throughout this decade,” continued Smith. “Together, these two trends are expected to fuel a substantial demand for cancer diagnostics. LabCorp wants to put in place the resources necessary to meet this demand and support the evolving needs of physicians and their patients.”

LabCorp is betting almost \$600 million that DIANON can be the platform around which it will build its cancer testing business. As it integrates DIANON, LabCorp will face several challenges.

First, DIANON’s business is organized to compete for tissue specimens that originate in physicians’ offices. It has developed a sales and marketing strategy that is different from that used by most commercial labs to compete for blood testing specimens.

Among other things, DIANON uses the “uncola” and “we’re number two—we try harder” marketing strategies developed by **Seven-Up** and **Avis** to compete against **Coca Cola** and **Hertz**, respectively. DIANON has positioned itself as a specialized lab provider that is *not* one of the two

# DIANON Built National Business Around Anatomic Pathology

## DIANON Systems, Inc.

### At-A-Glance

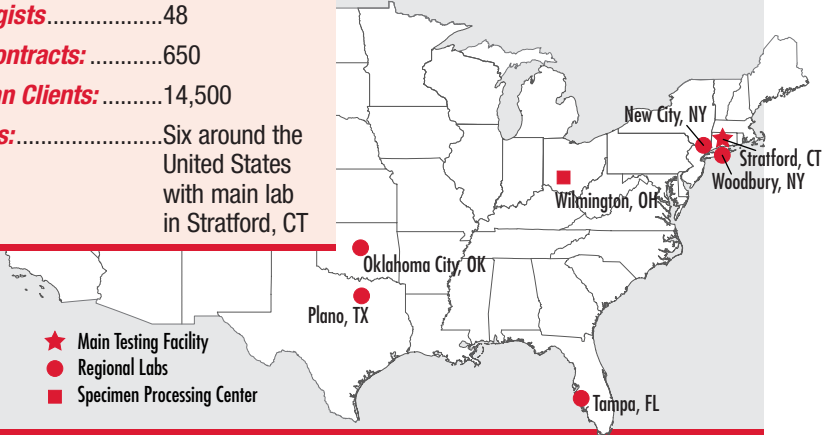
<b>Founded:</b> .....	1982
<b>Headquarters:</b> .....	Stratford, CT
<b>2002 Revenues:</b> .....	\$190 mil (estimated)
<b>2001 Revenues:</b> .....	\$125.7
	<ul style="list-style-type: none"> <li>• Anatomic Path: \$87.2 mil</li> <li>• Genetic Testing: \$19.8 mil</li> <li>• Clin Chemistry: \$18.7 mil</li> </ul>
<b>Volume:</b> .....	160,000 tissue specimens per month
<b>FTEs:</b> .....	1,800
<b>Pathologists</b> .....	48
<b>Payer Contracts:</b> .....	650
<b>Physician Clients:</b> .....	14,500
<b>Lab sites:</b> .....	Six around the United States with main lab in Stratford, CT

Almost 70% of DIANON Systems' annual revenues are derived from anatomic pathology (AP) services. Its specimens come primarily from physicians' offices. In recent years the company posted strong rates of growth in specimen volume that drove comparable gains in revenues and net earnings.

DIANON has been particularly successful in managed care contracting. Among its 650 payer contracts are major agreements with Aetna, UnitedHealthcare, and Oxford Health.

### Dianon's National Lab System

As the map shows, DIANON's business is centered mostly in the eastern half of the United States. The Ohio facility is a processing center located adjacent to the Airborne Express sorting hub.



blood brothers. Post-merger, it will be a LabCorp business unit. Can DIANON keep its identity and retain the majority of its existing clients?

Second, LabCorp states that it wants to incorporate the best of DIANON's CarePath information system. However, integration of information systems across multiple lab sites has been the source of much trouble and grief for

most lab companies. Can LabCorp integrate the best features of CarePath across its other business divisions in a timely and cost-effective manner?

Other challenges, including antitrust, may pop up. But at this moment in time, executives at LabCorp and DIANON are optimistic that this is a doable merger with lots of potential.

**TDR**

Contact Brad Smith at 336-584-5171.

# Why DIANON Sale Alters Anatomic Path Market

*LabCorp's \$598 million investment is a major bet on AP-based diagnostics*

**CEO SUMMARY:** *By acquiring DIANON Systems, LabCorp raises the level of competition for tissue specimens originating in physicians' offices. LabCorp's acquisition is also a validation of predictions that cancer diagnostics will be a high-growth segment of laboratory medicine. Anatomic pathologists have ample warning that new national competitors will soon attempt to capture local physician accounts.*

**W**ITHIN the anatomic pathology profession, news of the pending acquisition of **DIANON Systems, Inc.** by **Laboratory Corporation of America** is an earthquake that scores high on the Richter Scale.

It fulfills a long-standing prediction by **THE DARK REPORT** that the two blood brothers want to develop more business in anatomic pathology and have been laying groundwork to intensify their competition against local pathology group practices.

Simply put, anatomic pathology is a profitable business, particularly when compared to relatively low reimbursement levels for clinical lab testing. Since the mid-1990s, a handful of companies organized specifically to provide anatomic pathology services nationally have enjoyed phenomenal growth, not to mention significant profits and net earnings.

Their stories have been regularly chronicled in **THE DARK REPORT** to alert and inform pathologists. After all, companies like **UroCor**, **DIANON**,

**IMPATh**, and **AmeriPath** do represent a threat to local pathology groups. But they also represent an opportunity. By studying their successes and business strategies, local pathology groups can copy what works. Local pathologists can use this knowledge to improve the services they offer to their local medical community and improve their financial stability.

## **Regional Pathology Winners**

There are numerous examples of local pathology groups which are responding to the changing healthcare marketplace. These groups are building critical mass that allows them to finance an expanded menu of clinical services. They are fielding sales reps to sustain and increase the number of business relationships feeding specimens—and revenues—into the group. But there are too few of these regional pathology winners.

With its acquisition of **DIANON Systems**, **LabCorp** raises the competitive stakes. **LabCorp** has extensive managed care contracts. It has exten-

sive client relationships with physicians in communities throughout the United States. It has a large sales force that regularly visits all its clients. Once the DIANON acquisition is complete, LabCorp will use these additional capabilities to move tissue specimens from anywhere in the nation into a centralized pathology laboratory.

***Both LabCorp and DIANON believe that most cancer care will be delivered outside the hospital in physicians' offices and other ambulatory settings.***

LabCorp is spending \$600 million so it can to deploy those resources and increase the number of tissue specimens referred by its physician-clients to the post-merger LabCorp/DIANON. Any expansion of its market share in tissue specimens will come primarily at the expense of local pathology groups.

There is another strategic consideration driving the LabCorp/Dianon deal which is important for pathologists to understand. LabCorp sees oncology as an outpatient disease. In speaking to analysts last week, LabCorp Chairman and CEO Thomas P. Mac Mahon said "Both DIANON and LabCorp believe that cancer is really treated as an outpatient disease. Patients prefer to stay home as much as possible during the course of their treatment.

### **Outpatient Opportunity**

"We see the combination of LabCorp and DIANON as an opportunity to leverage our skill base in the outpatient physician community. Many of the cancer test licenses we've signed are for outpatients," explained Mc Mahon.

Alert pathologists understand the ramifications of this strategic vision.

With each passing year, more cancer care will move out from the hospital into outpatient/outreach settings. That is why LabCorp and DIANON both want to position themselves to benefit from this trend.

Over time, this trend puts many local pathology groups at financial risk. Hospital-based pathologists may have an automatic "lock" on inpatient specimens, but they must compete for outreach specimens.

Traditionally, in many cities there has been little true competition for tissue specimens originating in physicians' offices. Local pathology groups accessed those specimens because of their personal relationships with physicians and the absence of any serious competition.

That is changing. The multi-year success of DIANON Systems and IMPATH has attracted Wall Street's attention. LabCorp is investing more than a half billion dollars to position itself to compete more effectively for tissue specimens in the physicians' office segment. What has been a quiet market niche, occupied mostly by local pathology group practices, will soon become an intensely-competitive battleground for several well-financed national laboratory companies.

### **New Corporate Culture**

If this type of competitive situation develops, THE DARK REPORT believes it will begin to drive consolidation within the pathology profession. There were specific evolutionary forces which drove wide-scale lab consolidation, first in the commercial lab sector between 1987-1994, then in the hospital lab sector between 1995-1999.

In 2002, these same evolutionary forces are visible. If THE DARK REPORT is reading the tea leaves correctly, our industry may be ready to experience a wave of consolidation in the anatomic pathology sector.

# “Direct-to-Consumer” Ad Runs in *New York Times*

*IMPATH's first effort to reach consumers hits wrong chord with College of Am. Path.*

**CEO SUMMARY:** *Two pioneering advertising campaigns launched in September. Both Myriad Genetics and IMPATH targeted consumers with advertisements about diagnostic testing. In each case, the most vocal response to the advertising came from within the medical community. Within the pathology profession, IMPATH's full-page advertisement in the New York Times Sunday Magazine was not well-received by some.*

**D**IRECT-TO-CONSUMER advertising of diagnostic testing services is the new dynamic in the national marketplace for anatomic pathology services.

In the month of September, both **Myriad Genetics, Inc.** and **IMPATH, Inc.** placed advertisements in consumer publications. The objective was to educate consumers about the specific diagnostic laboratory testing services offered by each company.

However, in each case, this advertising attracted unfavorable attention by some health professionals. Their public response demonstrates that the concept of advertising diagnostic tests directly to consumers may still be ahead of its time.

Earlier this year, Myriad Genetics announced a two-city marketing test that started in September. Advertisements about its genetic screening tests target consumers in the Atlanta and Denver metropolitan areas. (*See TDR, June 24, 2002.*) News of the ad campaign caused some in the medical community to pub-

licly question the ethics of advertising genetic screening directly to consumers. Newspapers and other media gave these criticisms wide play.

Like Myriad Genetics, IMPATH's direct-to-consumer ads also attracted attention from within the medical community. On September 18, 2002, it ran a full-page advertisement in the Sunday magazine of the *New York Times*. The ad discussed the story of Artemis, a cancer patient whose tumor of unknown primary was not identified until her biopsy was sent to IMPATH.

## **Ad Generates A Response**

Within days of the ad's appearance, both IMPATH and the **College of American Pathology** (CAP) received complaints from irate pathologists. They were upset about the ad's characterization of the "community lab" and the implication that local pathologists could not provide the same level of sophisticated cancer diagnostics as IMPATH.

In the ten weeks since the ad first appeared, IMPATH has spent considerable effort to work with the College and



the pathology community to affirm and publicize its longstanding support of, and partnership with, pathologists in community hospitals throughout the United States.

## Learning New Lessons

As part of this process, both IMPATH and the pathology profession are learning that consumer-directed advertisements about diagnostic testing can be interpreted differently by different segments of the marketplace.

“These ads in the *New York Times* were IMPATH’s first effort to communicate directly with consumers,” stated Paul Esselman, Senior Vice President, Sales & Marketing at IMPATH. “Our strategic goal was to build recognition for the role that pathologists play in cancer diagnostics with the patient’s healthcare team. The ad was designed to emphasize the synergies that exist between local pathologists, a patient’s oncologist, and IMPATH’s services, while reinforcing the benefits of maintaining the patient in a community setting.

“What surprised us was the range of response generated by this ad,” he said. “In particular, it was perceived by some that we were shifting away from our core strategy of supporting community hospital-based pathologists while others understood the message we were trying to convey.”

## CAP Helped In Ad Redesign

In response to these concerns, during October, IMPATH and the College of American Pathology exchanged letters, which were made public on the CAP Web site. IMPATH, with input from the College, is redesigning the advertisement and will run the revised ad in the *New York Times* Sunday Magazine on December 8 and December 22, 2002.

“The objective of this revised ad is to reinforce the value of pathology services and help patients better understand the role pathologists play in

## Growing Consumer Interest Recognized by IMPATH

**I**N RECENT YEARS, growing numbers of consumers have contacted IMPATH directly for information on cancer. In part, it was this consumer interest which triggered the idea of a “direct-to-consumer” ad campaign.

“IMPATH receives a steady flow of emails, phone calls and letters from consumers requesting information about cancer and cancer diagnostics,” stated Paul Esselman, Senior Vice President, Sales & Marketing at IMPATH. “Lots of consumers and patients are using the Internet for research on cancer and that’s frequently how they learn about us.

“Many patients are hungry for more knowledge about cancer and how pathologists play a role in diagnosing cancer and other diseases. Our advertising campaign was a first step to provide information and help patients understand more how pathology services can help them if they are diagnosed with cancer,” said Esselman.

diagnosing cancer,” explained Esselman. “The College has given the revised ad a positive review.”

“IMPATH responsibly asked the College to review the revised ad,” stated Paul A. Raslavicus, M.D., President of CAP. “The upcoming ad will set the record straight on the important role of the community pathologist in healthcare.

“It’s essential that patients and consumers accurately understand pathology’s role,” noted Dr. Raslavicus. “Neither quality healthcare nor IMPATH can exist without good working partnerships with community pathologists.”

As a result of feedback from the original advertisement, IMPATH has gained a deeper appreciation for the importance of “staying on message” about the important and significant

# How IMPATH's "Direct-to-Consumer" Advertising Went Awry

(A) Below is the full page "direct-to-consumer" advertisement IMPATH ran in the *New York Times Magazine* on Sunday, September 8, 2002.



One morning Artemis awoke with a pain in her right hip, and everything changed. A scan by her orthopedist and a biopsy, analyzed by a community-based lab, revealed cancer of an unknown origin. Radiation and chemotherapy did not help. Artemis was faced with failed treatment and the probability that her cancer would spread to other parts of her body.

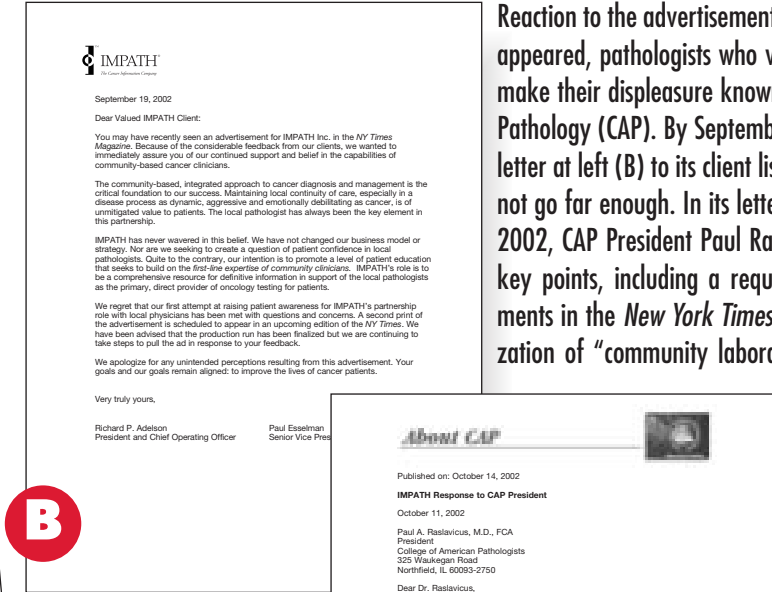
A friend recommended she have her biopsy specimen analyzed by IMPATH Physician Services. Within 48 hours of its receipt, we pinpointed the problem as medullary

carcinoma of the thyroid. The cancer in her thyroid had spread to her hip. Her doctor was notified. He confirmed IMPATH's interpretation of her pathology diagnosis with an ultrasound of her thyroid and recommended surgery. The tumor was removed and now Artemis wakes up with a smile and a bright future.

Our specialized analyses helped her get the right treatment at the right time.



Ask your doctor about IMPATH - Improving Outcomes For Cancer Patients and Their Doctors



September 19, 2002

Dear Valued IMPATH Client:

You may have recently seen an advertisement for IMPATH Inc. in the *NY Times Magazine*. Because of the considerable feedback from our clients, we wanted to immediately assure you of our continued support and belief in the capabilities of community-based cancer clinicians.

The community-based, integrated approach to cancer diagnosis and management is the critical foundation to our success. Maintaining local continuity of care, especially in a disease process as dynamic, aggressive and emotionally destabilizing as cancer, is of unrivaled value to patients. The local pathologist has always been the key element in this partnership.

IMPATH has never wavered in this belief. We have not changed our business model or strategy. Nor are we seeking to create a question of patient confidence in local pathologists. Quite to the contrary, our intention is to promote a level of patient education that seeks to build on the first-line expertise of community clinicians. IMPATH's role is to be a comprehensive resource for definitive information in support of the local pathologists as the primary, direct provider of oncology testing for patients.

We regret that our first attempt at raising patient awareness for IMPATH's partnership role with local physicians has been met with questions and concerns. A second print of the advertisement is scheduled to appear in an upcoming edition of the *NY Times*. We have been advised that the production run has been finalized but we are continuing to take steps to pull the ad in response to your feedback.

We apologize for any unintended perceptions resulting from this advertisement. Your goals and our goals remain aligned to improve the lives of cancer patients.

Very truly yours,

Richard P. Adelson  
President and Chief Operating Officer

Paul Esselman  
Senior Vice President



Published on: October 14, 2002

IMPATH Response to CAP President

October 11, 2002

Paul A. Rastlavicus, M.D., FCA  
President  
College of American Pathologists  
325 Waukegan Road  
Northfield, IL 60093-2750

Dear Dr. Rastlavicus,

Thank you for taking the time to express your concerns about IMPATH's ad in the *New York Times Magazine*.

Your perceptions are very important to us and we greatly appreciate your feedback. Please accept our apologies for any unintended perceptions that we sought to undermine patient confidence in, or diminish the role of, the community pathologist. Rather, we seek to encourage patients to engage in an active dialogue with their local physician to enhance confidence in the capabilities and diagnostic skills of community-based pathologists.

We are extremely proud to have built our business on the continued support and loyalty of our clients—one of our most valued assets. We work very hard to cultivate each relationship and foster a mutually beneficial partnership to help pathologists with their patients. It is quite contrary to the fundamental principle of our business model to detract from the expertise of community pathologists. Unlike some of our competitors who focus on supplanting this market, we do not continue our success without these partnerships.

In an effort to show our continued commitment to the pathology community, we intend to run a new advertisement demonstrating our dedication to community-based pathologists that will appear in two upcoming *New York Times Sunday Magazine* editions. Prior to finalizing the ad, we will ask you and several other members of the pathology community for your opinion to better gauge client feedback.

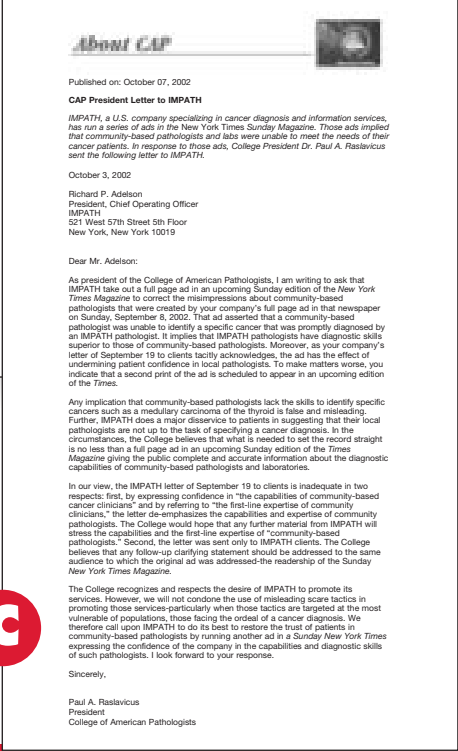
In addition, we are making every effort to ensure that future patient-directed advertising appropriately highlights the critical role of local pathology services and reinforces the partnerships that have been vital to IMPATH's success.

Again, let me reassure you that the content of the advertisement in no way reflects our strong support of community-based cancer care. We look forward to a continued relationship with the College of American Pathologists and its members and apologize for any inconvenience this may have caused you.

Sincerely,

Aru D. Saad, Ph.D.  
Chairman and Chief Executive Officer

Reaction to the advertisement at left was not what IMPATH expected. Once it appeared, pathologists who viewed this advertisement responded swiftly to make their displeasure known to both IMPATH and the College of American Pathology (CAP). By September 19, 2002, IMPATH felt the need to send the letter at left (B) to its client list. However, the College believed this effort did not go far enough. In its letter at bottom right (C) to IMPATH on October 3, 2002, CAP President Paul Rastlavicus, M.D. took IMPATH to task on several key points, including a request that IMPATH run two-full page advertisements in the *New York Times Sunday Magazine* to correct its mischaracterization of "community laboratories." IMPATH's response, in a letter dated October 11, 2002 at lower left (D), was to accede to CAP's request and commit to running two corrective advertisements. The revised ads will run in the *New York Times Sunday Magazine* on December 8 and December 22, 2002.



Published on: October 07, 2002

CAP President Letter to IMPATH

IMPATH, a U.S. company specializing in cancer diagnosis and information services, has run a series of ads in the *New York Times Sunday Magazine*. Those ads implied that community-based pathologists and labs were unable to meet the needs of their cancer patients. In response to those ads, College President Dr. Paul A. Rastlavicus sent the following letter to IMPATH.

October 3, 2002

Richard P. Adelson  
President, Chief Operating Officer  
IMPATH  
521 West 57th Street 5th Floor  
New York, New York 10019

Dear Mr. Adelson:

As president of the College of American Pathologists, I am writing to ask that IMPATH take out a full page ad in an upcoming Sunday edition of the *New York Times Magazine* to correct the misrepresentations about community-based pathologists that were created by your company's full page ad in that newspaper on Sunday, September 8, 2002. That ad asserted that a community-based pathologist was unable to identify a specific cancer that was promptly diagnosed by an IMPATH pathologist. It implies that IMPATH pathologists have diagnostic skills superior to those of community-based pathologists. Moreover, as your company's letter of September 19 to clients factually acknowledges, the ad has the effect of undermining patient confidence in local pathologists. To make matters worse, you indicate that a second print of the ad is scheduled to appear in an upcoming edition of the *Times*.

Any implication that community-based pathologists lack the skills to identify specific cancers such as a medullary carcinoma of the thyroid is false and misleading. Further, IMPATH does a major disservice to patients in suggesting that their local pathologists are not up to the task of specifying a cancer diagnosis. In the circumstances, the College believes that what is needed to set the record straight is no less than a full page ad in an upcoming Sunday edition of the *Times Magazine* giving the public complete and accurate information about the diagnostic capabilities of community-based pathologists and laboratories.

In our view, the IMPATH letter of September 19 to clients is inadequate in two respects: first, by expressing confidence in "the capabilities of community-based cancer clinicians" and by referring to "the first-line expertise of community clinicians," the letter de-emphasizes the capabilities and expertise of community pathologists. The College would hope that any further material from IMPATH will stress the capabilities and the first-line expertise of "community-based pathologists." Second, the letter was sent only to IMPATH clients. The College believes that any follow-up clarifying statement should be addressed to the same audience to which the original ad was addressed—the readership of the *Sunday New York Times Magazine*.

The College recognizes and respects the desire of IMPATH to promote its services. However, we will not condone the use of misleading scare tactics in promoting those services—particularly when those tactics are targeted at the most vulnerable of populations, those facing the ordeal of a cancer diagnosis. We therefore call upon IMPATH to do its best to restore the trust in the trust in community-based pathologists by running another ad in a *Sunday New York Times Magazine* expressing the confidence of the company in the capabilities and diagnostic skills of such pathologists. I look forward to your response.

Sincerely,

Paul A. Rastlavicus  
President  
College of American Pathologists

role pathology plays within community hospitals.

“There’s been a positive outcome,” observed Esselman. “We’ve been actively contacting clients and pathologists who use our services to reaffirm our commitment to them and partnership with them. We’ve also reached out to pathologists who were critical of the original advertisement to listen to their comments and provide more detail about our business philosophy and our intentions with the first advertisement.”

These early attempts by Myriad Genetics and IMPATH to use direct-to-consumer advertising to promote diagnostic tests have revealed one interesting fact. It is the medical profession which seems to be most sensitive to the concept of advertising health services directly to consumers. The “loudest” response to both companies’ ad campaigns came from medical professionals, not from consumers or consumer advocates.

## Educating Consumers

It is important to also note that these early efforts to educate consumers about diagnostic tests were created and funded by publicly-traded companies. These companies are highly motivated to build specimen volume. They are willing to invest money in advertising as a way to influence consumers by educating them about possible options.

By advertising lab tests directly to consumers, lab companies are following the example established by the pharmaceutical industry. Direct-to-consumer ads promoting prescription drugs now generate billion-dollar sales for such familiar brands as Claritin and Prilosec. Even as Prilosec loses its patent protection, its manufacturer is using a national consumer ad blitz to switch patients to its newest, patent-protected product. That is why ads for Nexium have become ubiquitous.

THE DARK REPORT believes the trend to advertise lab tests directly to consumers, now in its infancy, will continue to grow. Along the way, many mistakes will be made. That’s because little is understood about how consumers will react to advertising about products which are involved in the detection and management of disease.

## Ads About Pap Testing

Such knowledge and experience will only be developed through trial and error. One of the largest efforts to use advertising to educate consumers about a diagnostic test involved **Cytec Corporation’s** ThinPrep® ad campaign. Ads touting ThinPrep ran in women’s magazines during the launch of that test. Those ads were considered to be effective at boosting both awareness and consumer demand for Cytec’s test. But ThinPrep is a screening test, an enhancement to the conventional Pap smear that women recognize as a valuable and positive procedure.

In the case of cancer diagnostics, advertising to consumers involves a different emotion. Such advertising deals with cancer—which society considerable to be an unfortunate, tragic, and often fatal event. Will advertising such services directly to consumers be an effective way to educate them and motivate them to patronize the pathology company which ran the ad? Will such ads bring new business to the lab?

These are tough questions. The answers will come one ad campaign at a time. Because public laboratory companies are motivated to invest and experiment with direct-to-consumer advertising, they will be first to identify the benefits—and the drawbacks—of advertising diagnostic tests directly to consumers.

**TDR**

Contact Paul Esselman at 800-447-8881 and Paul A Raslavicus, M.D. at 800-323-4040.

# Diagnostic Assay Marketing

## Tenet's Outlier Medicare Fees Put It in Unwelcome Spotlight

**M**EDICARE CODING AND BILLING policies at **Tenet Healthcare Corporation** have come under scrutiny by both Medicare officials and Wall Street analysts.

Attention is centered around how Tenet aggressively pursued Medicare reimbursement under "outlier" formulas. These formulas are designed to supplement DRG reimbursement when a hospital treats patients with particularly complex health problems.

### Huge Jump In Outlier \$s

In 2000, Medicare paid Tenet \$351 million in outlier payments. This figure increased to \$763 million in fiscal 2002, an increase of \$451 million, or 117%, in 24 months!

Comparisons with other hospitals reveal the scale of Tenet's Medicare billing strategy. For fiscal 2002, 23.5% of Tenet's Medicare reimbursement came from outlier payments. At HCA, it was only 5% and 4.5% for all hospitals.

One technique Tenet used to boost its outlier reimbursement was to aggressively raise its chargemaster prices each

year. Although government and private payers don't pay chargemaster rates, it is chargemaster prices which are used in complex pricing formulas that trigger supplemental payments from Medicare, Medicaid, and other payers.

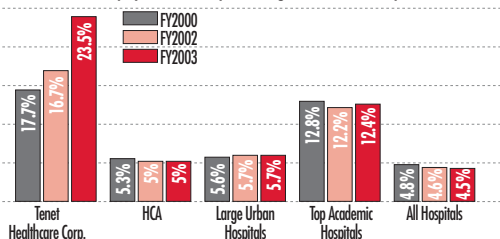
Federal auditors are now scrutinizing Tenet. Since news of this crisis became public, Tenet's share price has declined 73% from its 52-week high of \$52.50 on October third.

THE DARK REPORT observes that Tenet's problems demonstrate that any attempt to "game" the Medicare reimbursement system eventually attracts attention. The *Wall Street Journal* said that "Tenet reaped rewards by triggering a hidden jackpot in the Medicare system."

Expect this to remain a major story. In California, FBI agents raided Tenet's **Redding Medical Center** and the offices of two cardiologists accused of performing unnecessary surgeries. Medicare's top administrator, Tom Scully, has said that fixing the outlier loophole is "now number one on my list of things to do." **TDR**

The chart at right shows why Tenet Healthcare caught the attention of Medicare regulators. Not only has it seen huge year-to-year increases in its Medicare outlier payments, but its percentage of Medicare outlier payments is twice that of academic hospitals and five times the percentage that HCA receives.

Medicare outlier payments as a percentage of Medicare inpatient revenue



Note: Years are Federal fiscal years; 2003 figures are estimated.

Source: UBS Warburg analysis of figures from the Centers for Medicare and Medicaid Services

# Academic Center Lab Implementing Six Sigma

*Management system is expected to accelerate gains in laboratory quality and productivity*

**CEO SUMMARY:** Fairview-University Medical Center's laboratory may be the nation's first academic center laboratory to deploy Six Sigma and Lean management systems. Administration expects Six Sigma to accelerate the rate at which improvements in quality and productivity can be realized. The laboratory's first black belt candidate is in training and enthusiasm is building among the laboratory staff.

SIX SIGMA and "Lean" management methods have arrived at **Fairview-University Medical Center Clinical Laboratories (F-UMC)**, located in Minneapolis on the University of Minnesota campus.

As a rule, academic center hospitals are not early adopters of cutting-edge management systems developed by corporations outside healthcare. Intrigued by this unusual development, THE DARK REPORT recently traveled to Minneapolis to learn, first-hand, what motivated administration at this academic center to introduce the principles of Six Sigma and Lean into its laboratory.

## Principles Already Known

"Although we may be the first academic hospital laboratory to employ Six Sigma, these management principles are not new to our health system," said Rick Panning, Administrative Director of Laboratory Services at **Fairview Health Systems**, which owns seven hospitals and 35 clinics in Minnesota.

"Over several years, Fairview's administrators and managers have un-

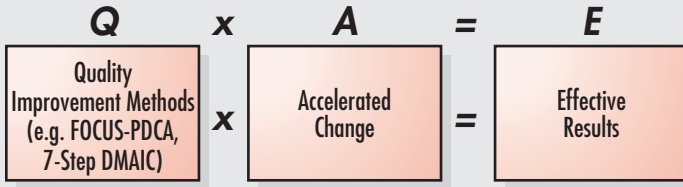
dergone regular and extensive training in advanced management systems," Panning said. "This includes education provided by **Motorola University** and the **Juran Institute**. **Blue Fire Consultants** has also provided training and consulting support. In addition, Fairview has long used the FOCUS-PDCA process improvement model when addressing change.

"Fairview Health System keys this training around what it calls 'Performance Excellence'," he continued. "We have a formula that emphasizes how quality management methods generate accelerated change to achieve effective results. (See sidebar on next page.) Our system uses this message to emphasize the importance of continuously improving patient care and raising service to higher levels.

"This is why the decision to introduce Six Sigma and Lean management techniques into the laboratory is simply one more step in Fairview Health System's ongoing management evolution," noted Panning.

## Quality Management Already Entrenched At Fairview Health

### *The Building Blocks of Performance Excellence*



*Fairview Performance Excellence*

▲ Above is the formula used at Fairview Health Systems to encourage the use of quality management methods and techniques to drive change within departments. Deming-based management tools are well-established within Fairview.

#### Fairview Health System's Balanced Scorecard

*Looking at what we do from a:*

- Customer perspective**  
*How do our customers view Fairview?*
- Process perspective**  
*In what processes should we excel in order to succeed?*
- Learning and innovation perspective**  
*How will we sustain our ability to serve our customers, to change, and to improve?*
- Financial perspective**  
*How does Fairview look to its stakeholders?*

◀ In evaluating progress toward goals, managers within Fairview Health System use the scorecard at left. Initiatives to improve clinical care, patient safety, and revenue cycle improvement must address these four perspectives. Quality management methods are the tools used to achieve results.

But why was Six Sigma selected over other management options, and why now? "There's a simple answer to that question," responded Panning. "Our administration wants to accelerate the results that come from using quality management tools. It believes that Six Sigma and Lean are management systems which generate faster and bigger gains in quality and productivity than the management methods we've used to date.

### Lab Challenged To Improve

"Our administration is challenging us to measurably improve the quality of our laboratory services even as we eliminate unnecessary costs," he added. "To help us achieve this, administration is willing to fund the expenses necessary to train our laboratory staff in Six Sigma and finance these black belt projects.

Compared to many other hospital labs, we are fortunate in that respect."

Panning explained that administration at Fairview sees management training as a worthwhile investment. "The cost of implementing Six Sigma and Lean will be more than recouped by the faster, larger gains in quality and productivity. The laboratory was singled out as the Six Sigma beta site for two main reasons. First, we are preparing to redesign the lab facility to accommodate automation. Second, we recognize that, if we can simplify the complex work processes in the laboratory, we can maximize efficiency and improve service," he explained.

"Administration also supported working with a key vendor in the laboratory to help us in that effort," continued Panning. "That's one reason **Johnson &**

**Johnson's Ortho-Clinical Diagnostics** division was selected to provide guidance and training in Six Sigma and Lean. It was important to our administration that Johnson & Johnson is committed to implementing Six Sigma and Lean throughout its own company."

### **First Black Belt Candidate**

Approval for the laboratory's first black belt project came in early spring. "The lab sent four individuals to champion training," noted Kathy Hansen, Director of Laboratory Operations at F-UMC. "Cindy Hudson, a supervisor in the acute care laboratory, was selected to be our first black belt candidate. Things have moved swiftly. Over the summer we completed Lean training, the lab underwent Value Stream Mapping, and the first black belt project was selected."

"This project's goal is to improve how we handle specimens passing through the acute care lab at Fairview-University Medical Center," said Panning. "F-UMC handles a high level of patient acuity because large numbers of solid organ and bone marrow/stem cell transplants and other complex cases are performed here. So it is important for the lab to sustain a high quality of service. Our first black belt project covers work flow from when the laboratory receives a specimen until it is ready for testing."

### **Lab Staff Likes Six Sigma**

"What's been a pleasant surprise is the genuine enthusiasm and support of our lab staff to the arrival of Six Sigma and Lean," added Panning. "During Value Stream Mapping, it was observed that our lab has many non-standard work processes and variation in sample delivery pathways. We've identified multiple interruptions in workflow, problems with our laboratory layout, and unnecessary handling and movement of specimens. There are plenty of opportunities to achieve substantial improvement."

"Along the way, analysis done with the Six Sigma and Lean tools validated that most of what we do in our lab is functioning at a high level already. It's affirmation to our staff that the quality management tools they've been using have kept us ahead of the curve."

Once Fairview's administration has evaluated outcomes from this first Six Sigma effort in the laboratory, it is prepared to roll out these techniques in other areas of the health system. "We are poised to introduce this into one of our community hospital labs in 2003," stated Panning. "We also see opportunities in transfusion services, microbiology, specimen processing/triage center, and in pre-analytic functions at all our system's laboratory sites."

### **Questioning The Status Quo**

During THE DARK REPORT's site visit to F-UMC, enthusiasm for the Six Sigma/Lean initiative was universal. Laboratorians, physicians, and administration are embracing these tools as aids in achieving quality and productivity goals. The willingness to rigorously question existing ways of doing business sets F-UMC apart from many academic center hospitals.

The reason for this support probably can be attributed to the extensive training in basic quality management philosophies and methods that Fairview has provided over the years to staff and physicians alike. Throughout the health system, stakeholders recognize how these tools can help improve work processes, reduce cost, and improve patient outcomes.

Fairview Health System is not the only early adopter applying Six Sigma methods in its laboratory. As many as 10 or 15 hospitals and health systems nationally have begun to implement Six Sigma and Lean methods.

**TDR**

Contact Rick Panning at 612-672-2751 and Kathy Hansen at 612-273-5090.

## Lab Industry Briefs

*Editors Note: There's increasing pressure for the American healthcare system to deliver improved healthcare outcomes in a cost-effective manner. Not surprisingly, laboratory testing is recognized as a high-impact, low-cost way to accomplish both goals. Here's a sampling of important healthcare initiatives which emphasize lab testing as essential to higher quality healthcare.*

### **FDA APPROVES 20-MINUTE HIV-1 TEST DEVELOPED BY ORASURE TECHNOLOGIES**

HAVING GAINED FDA APPROVAL for its point-of-care HIV test, **OraSure Technologies, Inc.** announced a co-distribution agreement with **Abbott Laboratories** that covers the United States.

Called OraQuick®, the test requires a finger stick of whole blood. Clinical data submitted to the FDA indicates that the OraQuick HIV test is 99.6% sensitive and 100% specific. It takes 20 minutes to generate a result. Positive tests must be confirmed using other methodology.

Initial use will be in hospitals and larger health clinics. But its ease of use is such that **Health and Human Services** Secretary Tommy Thompson has urged OraSure to apply to the FDA for a waiver. AIDS advocacy groups support this move because it would allow the test to be used in more settings, such as in mobile testing vans and at HIV counseling centers staffed by social workers.

Health officials want a rapid HIV test that is simple to use and can generate an immediate and accurate result. Currently at least 8,000 people per year are tested for HIV, but never return to get their results. It is also expected to be useful in many point-of-care situations. For example, women who weren't checked for HIV earlier in their

pregnancy could be tested in the delivery room. This could permit newborns of infected mothers to immediately get HIV-blocking medication.

### **C-REACTIVE PROTEIN TO PLAY GREATER ROLE IN CARDIOLOGY TESTING**

SOON MANY AMERICANS may know as much about their C-reactive protein (CRP) levels as they do about their cholesterol levels. As this happens, laboratories around the country will begin to perform more C-reactive protein testing.

New clinical studies provide evidence that even people with low levels of the "bad" cholesterol LDL may be at higher risk of cardiovascular diseases if their C-reactive protein levels are elevated. Some experts believe that as many as 30 million Americans may have normal LDL levels, but elevated C-reactive protein.

Officials at the **Centers for Disease Prevention** (CDC) and major cardiology associations are in the process of drafting revised clinical protocols that incorporate CRP testing. These new protocols are expected to trigger major changes to how physicians evaluate patients for heart disease. Laboratorians should track this story as it unfolds.

One clinical study which drew attention to CRP's role in heart disease was the multi-year Women's Health Study. Results were published recently in the *New England Journal of Medicine*. Blood samples from 28,000 women were used to evaluate the relationships between C-reactive protein (CRP) and heart disease. CRP scores below one had the lowest risk. Scores above 3 were highest risk.



“Across the board, CRP proved to be a better predictor (of heart disease) than LDL,” stated Paul M. Ridker, M.D., author of the study and Director of the Center for Cardiovascular Disease Prevention at **Brigham and Womens’ Hospital** in Boston, Massachusetts.

### **DIABETES GROUPS PUSH MORE USE OF HbA1C IN EDUCATIONAL EFFORT**

IT’S A WELL-ESTABLISHED TEST that’s about to gain a higher profile. Several diabetes associations, with funding from a major pharmaceutical company, have launched a public relations campaign to encourage people to do more HbA1C testing.

The campaign is called “The Diabetes A1C Initiative.” It has two primary goals. The first goal is, over a two-month period, to raise awareness about A1C as a measure of blood sugar control. The second goal is “to educate people about the need for, and benefits of, reaching an A1C less than 7%.” This is the target for proper blood glucose control, as recommended by the **American Diabetes Association**. **Aventis Pharmaceuticals** is providing funding for the initiative.

As with heart disease, the numbers are affected people are huge. At least 17 million Americans have diabetes. Another 15 million more are considered to be pre-diabetic—with blood sugar levels above normal, but not yet diabetic.

During the next several years, clinical laboratories should expect to see increased interest by patients in learning more about HbA1C testing. Because of the recommendations of health professionals, the volume of HbA1C testing done annually in the United States will probably also increase.

### **CANCER SOCIETY ISSUES NEW GUIDELINES FOR PAP TESTING**

ON NOVEMBER 14, 2002, the **American Cancer Society** (ACS) issued new guidelines affecting when and how often women should be screened for cervical cancer. These have been published in the November/December 2002 issue of *CA A Cancer Journal for Clinicians*.

Based on the new recommendations, most women would begin cervical cancer screening later, have an option to stop at a certain age (70 years), and be exempt from screening entirely if they have had a hysterectomy.

“The new guidelines will have a major impact on the number of women who are over-screened and over-treated,” said Mary A. Simmonds, M.D., President of the ACS. “Because most cervical precancers grow slowly, having a test every two to three years will find almost all cervical pre-cancers and cancers while they can be removed or treated successfully.”

ACS also noted that the big issue in cervical cancer screening is not the sensitivity of existing tests, but reaching women who currently are never tested. “The biggest gain in reducing cervical cancer incidence and mortality would be achieved by increasing screening rates among women who have not been screened or who have not been screened regularly,” observed Dr. Simmonds.

The ACS estimates that 13,000 women will develop invasive cervical cancer this year and some 4,100 women will die of the disease. About half the cervical cancers diagnosed annually in the United States are in women who have never been screened.

The new guidelines also recognize that new cervical cancer screening technologies, like liquid preparation Pap smears and HPV testing, can play a role in early detection.

# INTELLIGENCE

**LATE & LATENT**  
Items too late to print,  
too early to report



Antitrust regulators are signaling displeasure about a growing number of business activities in healthcare. Timothy Muris, Chairman of the **Federal Trade Commission (FTC)**, was in Chicago on November 7 to address a group of lawyers and business people. He told them that the FTC “continues to see a wide variety of overt anticompetitive behavior in healthcare, along with some new variants.”

## **MORE ON: Antitrust**

In September the FTC formed a special task force specifically to evaluate completed hospital mergers to determine if they engaged in anticompetitive behavior following completion of the merger. As of press time, the FTC was also continuing its review of the acquisition of **Unilab by Quest Diagnostics Incorporated**. It is known that the FTC has antitrust concerns about the proposed deal, which was announced last April.

## **HAND-WASHING OUT FOR DOCS & NURSES; ALCOHOL GEL IS IN!**

It’s another paradigm shift away from a long-standing practice. Lots of healthcare workers knew this was coming, but now it’s official. The **Centers for Disease Control and Prevention (CDC)** issued new guidelines for infection control late last month which specify that alcohol-based gels and solutions can be used for hand hygiene. “We’ve learned that using alcohol-based products improves adherence to hand hygiene,” noted Julie Gerberding, Director of the CDC. Studies show use of these products in hospitals can potentially cut existing infection rates by half.

## **“LAB TESTS ONLINE” MOVES UP ON GOOGLE**

Here’s another sign of change. The **American Association of Clinical Chemistry (AACC)** disclosed that its vendor-sponsored Web site *Lab Tests Online* is now

**Google’s** top-ranked site for lab testing information. It has also risen to a number two ranking in the Google Directory listing for Patient Education. [www.Labtestsonline.net](http://www.Labtestsonline.net) is a worthy effort described as “a public resource on clinical lab testing from the laboratory professionals who do the testing.”

## **MORE FUNDING FOR MED TECH TRAINING**

In Ontario, Canada, the provincial government announced \$1 million in funding to expand training of medical technologists. Toronto’s **Michener Institute for Applied Health Sciences** will receive the funds to train 32 new med techs by 2005. Within the province, there are currently 250 vacancies for med techs at 93 hospitals. Another 100 vacancies exist at private labs.

*That’s all the insider intelligence for this report.  
Look for the next briefing on Monday, December 9, 2002.*

## ***News About The Next War***

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