

From the Desk of R. Lewis Dark...

THE **RD**ARK **REPORT**

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

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R. Lewis Dark

Founder & Publisher



Anatomic Pathology May Be “Hot” Opportunity

EVERY NOW AND THEN, IT HELPS TO STAND BACK and look at the big picture. On pages 9-14 in this issue, you will read a unique assessment of the lab industry and pathology profession prepared by our Editor-In-Chief.

His analysis covers three points. First, he sorts the market for lab and pathology testing into four segments, then identifies the major competitors in each market. That alone is interesting reading, because many lab executives and pathologists may not realize that there have been fundamental and deep-reaching changes in competition.

Second, he “guess-timates” market shares for each market segment. That’s a tough challenge because, as most of us know, comprehensive and accurate numbers for total lab testing in the United States are tough to come by.

Three, our Editor offers observations and predictions about the future evolution of the competitive marketplace for clinical lab testing and anatomic pathology services. In particular, he notes that competition for physicians’ office testing is increasingly a battle between the two national labs and hospital/health system lab outreach programs in city after city around the country. Editor Michel believes that the era of the local, pathologist-owned independent commercial laboratory has ended.

But what I found most intriguing is his analysis of the anatomic pathology (AP) marketplace. He estimates that physicians’ office-originated AP specimens are a \$3 billion market. Notably, the two blood brothers, **AmeriPath**, **DIANON Systems**, **IMPATH**, and **UroCor**, combined, have an estimated \$914 million, almost one-third, of this market already.

This was certainly not the case as recently as 1995, when AmeriPath didn’t exist, DIANON was primarily a clinical lab company, and IMPATH was in the midst of its IPO (initial public offering). Of course, **Quest Diagnostics Incorporated** and **Laboratory Corporation of America** were certainly important competitors in this AP testing segment at that time.

I’d say the success of national AP companies at capturing ever-growing numbers of specimens from the docs’ offices in recent years is an important development. There’s a good argument that, at this moment, anatomic pathology is the “hot” market in diagnostic services. For local anatomic pathology groups, that spells both danger and opportunity. A “do-nothing” strategy may cause them to lose their local revenue base. A proactive marketing strategy can provide financial stability and growth.

DIANON Acquires UroCor And Boosts Urology Share

DIANON Systems becomes the “big dog” in the market for urology-based AP services

CEO SUMMARY: *Following years of intense competition for the diagnostic testing business of office-based urologists, DIANON Systems and UroCor will now join forces. The recently-announced merger creates a powerhouse anatomic pathology company in the urology-based diagnostics services market. This merger also demonstrates that the market for anatomic pathology services remains robust.*

FOR MORE THAN THREE YEARS, DIANON Systems, Inc. has sought a marriage with UroCor, Inc. That courtship finally ended with the announcement on June 29 that the two companies would merge.

DIANON Systems will pay approximately \$180 million to acquire UroCor. DIANON and UroCor had revenues of \$95.7 million and \$52.6 million, respectively, in 2000.

The deal is subject to regulatory clearance and shareholder approval. Post-merger, DIANON Systems will be the nation's largest provider of diagnostic services to office-based urologists.

“Everyone's quite excited about this deal,” stated Kevin Johnson, DIANON's President and CEO. “For several years, we've posted a strong financial perfor-

mance. UroCor has turned its financial corner and is also doing well. That's a great foundation to build upon.”

Within the anatomic pathology profession, the DIANON-UroCor merger demonstrates that the national market for pathology services continues to be robust. Johnson believes that the sum of the two companies will be more than the parts.

“Both companies are known and respected for outstanding quality and customer service,” observed Johnson. “Because of our similar business structures, there is significant opportunity for cost synergies and cross-selling to increase overall sales volume.”

“DIANON is focused on five clinical specialties—urology, gastroenterology, oncology, dermatology, and ob-

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gyn,” he said. “The diagnostic testing services performed by UroCor’s main lab in Oklahoma City will be broadened to include these five specialties.

“I would also like to point out that UroCor has an excellent team of pathologists and laboratory technologists,” explained Johnson. “With today’s tight labor market, that’s an invaluable asset that will play an essential role in supporting the continued growth of our combined company.”

Broadening Lab Services

DIANON already has experience at taking a single-specialty anatomic pathology laboratory and broadening its service menus. In recent years, DIANON has quietly built a network of five laboratories that complement its main lab facility in Stratford, Connecticut.

“We’ve had the opportunity to do strategic lab acquisitions. In every case, we’ve expanded the diagnostic services offered from those labs,” noted Johnson. “These labs are linked by a uniform information system. Over time, each of these labs has seen a hefty increase in business volume.”

Although both UroCor and DIANON have competed against each other for years, each company had a very different business strategy. UroCor was organized exclusively to serve the needs of office-based urologists. It wanted to offer both diagnostic services and therapeutic products to urologists. It was also willing to provide administrative services, such as billing and collections, as a way of becoming a value-added partner to its urologist clients. (See *TDR*, June 23, 1997.)

Five Clinical Specialties

In contrast to UroCor’s single-specialty business focus, DIANON Systems aimed at providing anatomic pathology and clinical lab testing services to the five key medical specialties mentioned earlier.

The competitive point of intersection was urology. Sales reps from both companies worked hard to convince urologists to use one lab over the other. Both companies devoted considerable resources to this sales battle.

During the first half of the 1990s, UroCor’s strategy played out well. At a time when financial turmoil and widespread bankruptcies plagued commercial laboratories across the country, UroCor was growing and profitable. During this time, it was listed four consecutive years as one of *Inc. Magazine’s* “Five Hundred Fastest Growing Private Companies.”

However, by 1998, two business decisions were coming back to haunt UroCor. Its foray into contract billing and collections for urology practices went poorly. The company pulled the plug on that business activity and posted a large loss.

Receivables Write-Down

Even as that was occurring, UroCor was dealing with the negative consequences of another business decision. As managed care contracts became an important part of the marketplace in the mid-90s, UroCor had decided to bring in specimens from cities where they were not a contract provider.

However, getting paid by these managed care plans proved to be an impossible task. During 1998 and 1999, the company was forced to write-off large amounts of its receivables. It was not until 2000 and 2001 that UroCor began to again post profits.

During this same time, DIANON’s business strategy worked well. Since the mid-90s, the company has generated steady year-to-year gains in both revenues and net profits.

Its business strategy of serving five clinical specialties gave it a larger business base. Also, DIANON decided that it would not pursue specimens

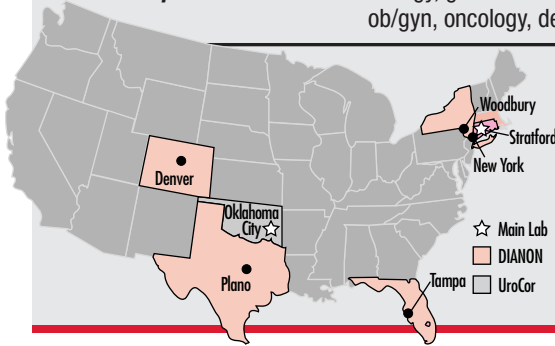
How DIANON & UroCor Stack Up

Merger At-A-Glance

DIANON SYSTEMS
Diagnostic Innovations for Medicine

UROCOR LabsSM
DIAGNOSTICS AT THE CORE OF YOUR PRACTICE

	DIANON Systems, Inc.	UroCor, Inc.
Revenues in 2000	\$95.7 Million	\$52.6 Million
Employees	681 FTEs	352 FTEs
Sales/Marketing	94 FTEs	111 FTEs
MD/PHD	49 FTEs	10 FTEs
Lab Locations	Stratford, CT; Tampa, FL, New York, NY; Woodbury, NY; Englewood, CO; Plano TX	Oklahoma City, OK
Clinical Specialties Served	Urology, gastroenterology, Urology ob/gyn, oncology, dermatology	



After the merger, the combined company's national anatomic pathology laboratory system will be anchored by the main laboratories in Stratford, Connecticut and Oklahoma City, Oklahoma.

until it was a managed care contract provider. Accordingly, it spent more than two years working with a number of large health plans. Notably, it earned carve-out status with **Aetna-U.S. Healthcare** and **Oxford Health Plans**. Specimens generated by these contracts have made a substantial contribution to DIANON System's revenue growth.

Impact On Pathology

For the anatomic pathology profession, the merger of DIANON Systems and UroCor has interesting consequences. It shows that the marketplace continues to support national anatomic pathology (AP) companies. Specimen volume growth by both companies has been consistent in recent years. These specimens are coming at the expense of local pathology group practices, which are

failing to react to the changing competitive service levels introduced in their area by national AP companies.

THE DARK REPORT believes that the success of national anatomic pathology companies reflects a shift in thinking by growing numbers of office-based physicians. These doctors perceive that they get a greater range of clinical and operational services from national AP firms.

For local pathologists to compete with the national AP firms on a level playing field, it will require the creation of more regional pathology supergroups. This provides the operational support and resource base necessary to offer expert pathology subspecialty services to clinicians.

TDR

For further information, contact Kevin Johnson at 203-381-4905.

8 “Must Have” Features For Web Lab Test Reports

Early-adopter labs learn important lessons about choosing the right Web-accessed system

CEO SUMMARY: *A growing number of laboratories have implemented Web-accessed lab test reporting for their office-based physician clients. Having participated in the design, sale and installation of many of these systems, Cory Fishkin gained valuable insights into the “do’s & don’ts” of Web-accessed lab test results reporting. In this first of several features, Fishkin identifies eight “must have” features.”*

USE OF THE WEB BY PHYSICIANS to access laboratory test results is becoming more common throughout the United States and Canada.

“It should come as no surprise that Web-accessed lab test results reporting is an easier service to implement than Web-accessed lab test ordering,” said Cory Fishkin, President of the newly-formed **Mostly Medical, Inc.**, based in New York.

“For that reason, Web-accessed lab test results reporting systems between labs and their physician office clients are more common than Web-accessed lab test ordering systems,” he added. “I believe this will continue to be true into the near future.”

Market Knowledge

Fishkin is intimately familiar with the market for Web browser-based systems for lab ordering and results reporting. He’s worked at a number of companies that pioneered such systems. Most notably, Fishkin was part

of **Abaton.com** prior to, and after its acquisition by **McKesson, Inc.** (formerly called **McKesson HBOC**).

First in a special series on Web-accessed lab test results reporting systems.

Now in his own consulting practice, THE DARK REPORT asked Fishkin if he would share his experience and insights on the subject of Web-accessed lab test ordering and results reporting. This first installment deals with the “must have” features for Internet-based lab test reporting systems.

Future installments will address order entry “must haves,” pricing arrangements, contracting strategies, and how physicians and their staffs react to these products. These briefings will provide clients and members of the Dark Intelligence Group with insider knowledge about issues that will help them make informed decisions.

Since most labs chose lab test reporting as the first Web-based service to implement, this series starts by looking at the functions that such systems should offer.

“Because these types of software systems are still new, labs must be careful to match the unique needs of their physicians’ office marketplace with the right product,” stated Fishkin.

POL Test Data Entry

“For example, many of the products offered by LIS vendors will not allow a physician’s office to enter POL lab test data into the system,” he explained. “Yet several of the connectivity vendors offer this feature. If many of the lab’s clients do lots of in-office testing, this capability may give the lab a competitive edge in that market.

“Based on my experience with labs to date, I believe there are eight ‘must have’ functions for an effective Web-accessed lab test reporting system,” Fishkin added.

“First on my list is the ‘inbox’ function. Basically, this presents, in one screen, all the test results received since the doctor last logged on,” he observed. “A well-organized inbox function is critical. Its primary benefit to doctors and their staffs is in preventing things from getting lost.

“A good inbox permits sorting by all factors: criticals, abnormal, stats, type of test, date, time, doctor, and more,” said Fishkin. “The inbox feature should allow fast toggling between the master patient list and individual patient results.

“It should also allow the physician to create an e-mail note and distribute it to his staff,” he added. “This avoids the sticky notes on charts and reports. This is also a feature demanded by physicians. As a result, about 75% of the lab test reporting systems now offer this feature.

Fast Screen Refresh Rates

“Number two is the system’s ability to perform within the unique setting of the individual physician’s office,” Fishkin stated. “The primary gauge of this is screen refresh, which should

Fishkin’s List of “Must Haves”

HERE ARE THE EIGHT FUNCTIONS which Cory Fishkin, President of Fishkin Consulting Associates, identifies as “must haves” for a successful Web-accessed lab test reporting system.

- 1** Ability to function speedily in a physician’s office environment with a fast screen refresh rate.
“In-box” which is well organized and allows sorting by categories such as criticals, abnormal, type of test, patient, etc.
- 2** Ability to deliver CLIA-compliant test reports which meet legal requirements and can be re-accessed in the future without change.
- 3** Cumulative test reporting.
- 4** Ability to enter and store results of tests performed in the doctor’s office, including POL interface capability.
- 5** Interpretive clinical information for physicians and patients; protocols for physicians.
- 6** Data base search capability that permits searching across all patients for specific test results and other attributes.
- 7** “Ease of use” as defined by intuitive screens, simple-to-execute functions.

take no longer than eight seconds. If it takes longer than that, both doctors and their staffs will simply not use the system to its full potential.

“I must stress the importance of performance. There are studies which document the fact that, if people must wait more than eight seconds to get to the next step, they will stop using that method and seek a faster way,”

Three classes of Vendors Offer Web Reporting Products

“IN THE LAST YEAR OR SO, vendors marketing Web-accessed lab test resulting systems have cleaved neatly into three categories,” commented Cory Fishkin, President of Mostly Medical, Inc.

“The first category is made up of the big healthcare information companies and LIS vendors,” he said. “These include companies like **Cerner, Sunquest, McKesson,** and the like.

“The second category are connectivity firms, aiming exclusively at the lab test ordering and results reporting market,” explained Fishkin. “Examples of these companies are **Atlas Development Corporation, LabDat.com, Labtest.com, LabPortal.com,** and others.

“Companies offering electronic medical record (EMR) systems have functionality for lab test reporting, but they are still building a market for their products and don’t have lab intensive experience for order entry,” added Fishkin. “That leaves home-grown lab solutions that may work only in the lab setting they were designed to serve.”

explained Fishkin. “Also, if it takes too many screens to actually access test results, this discourages people from regularly using the system.

“So performance is critical. Some lab test reporting systems require broadband Internet access, like cable or DSL, to deliver acceptable screen refresh rates,” he said. “For labs in metropolitan areas like New York or Los Angeles, this might be okay. But in areas where most doctors’ offices use modem dial-up, that same system may not be acceptable.

“By the way, in the evenings, when doctors are dialing in from their homes, they tend to be more tolerant of

slower systems than when they use it in their office,” added Fishkin.

“My third ‘must have’ function is the ability to deliver CLIA-compliant lab test reports,” noted Fishkin. “The lab industry has a definition of a legal, hard copy test report. Yet a number of Web-accessed lab test reporting systems currently available in the market cannot meet this requirement. You want to look for a system which has this capability. It should also be able to deliver an exact copy of that report in the future (without changing important information like the patient’s name if it changes because of marriage, etc.).

Automatic Printing

“The other reporting capability which is essential is automatic printing,” he added. “The system should periodically retrieve the currently available test results and print them out. This feature is a major issue for browser-based systems. Because a browser works in a thin client setting, generally it can’t tell a personal computer what to do. A separate software program must be installed on the PC’s hard drive to perform this function.

“Cumulative reporting is the fourth essential function,” declared Fishkin. “In my experience, this is the sizzle feature which impresses the doctors. However, once the test reporting system is installed, only a relatively small number of physicians actually use this feature in practice. But these doctors will use it continually and, over time, other colleagues in the office will begin to use this feature. With the growing emphasis on improving test utilization and disease management programs, I predict this will become a much more important function over time.

“Number five is compatibility with physician office laboratories (POLs),” he commented. “At its simplest, this involves a screen which allows the doctor’s lab tech to enter data from tests

such as urine dipsticks and PTs. But it can also involve a direct interface with the information systems of larger POLs.

“The objective is to merge the physicians’ office test results so that the doctor only has to go to one place to see *all* the lab results on his patients,” Fishkin said. “This eliminates the paper jumble in the medical charts and brings a consistency to the test results which physicians quickly come to appreciate.

“I should point out that providing this lab data capture feature for POL testing may trigger legal and compliance issues,” added Fishkin. “Labs should do proper legal due diligence before offering this type of service to physicians’ office clients.

“The sixth ‘must have’ function is interpretive clinical information,” he noted. “Both doctors and patients should have appropriate information, accessed by hyperlinks from the lab test reports. If lab testing protocols are used by an organization, having them integrated into the application is a big plus. Don’t underestimate consumer interest in their lab tests nor the growing number of physicians who want fast access to relevant clinical information about the tests they are ordering.

“Number seven is the ability of the system to search across patients,” noted Fishkin. “For example, can I find all patients with a total cholesterol over 250? Which patients have not been tested during the past two years?”

Physicians Will Use it

“A number of Web-based lab test reporting systems are beginning to promote this capability,” he explained. “However, I believe that once physicians have this tool, they will use it. It will keep patients from slipping through the cracks in a busy practice and will allow physicians to identify patients who are appropriate for clinical trials. I also

think laboratories which are first to offer this feature will have competitive advantage in the marketplace.”

“I saved ‘ease of use’ for the last of my eight ‘must have’ functions,” noted Fishkin. “I define this in a very specific way. For the doctor and his staff, the browser-based reporting system must be intuitive and require almost no training. Every window, label, and button in the system must be understandable to the average person,” he said.

“As the user moves from window to window, it should be both obvious and simple for them to understand what they are to do,” noted Fishkin. “Doctors demand this type of simplicity. It is probably the number one attribute that doctors want from a lab test reporting system.

List Is A Starting Point

“I recommend using this list of eight ‘must have’ functions as a starting point to review products your lab might be considering,” noted Fishkin. “Vendors have learned some important lessons since the first generation of these Web-accessed lab test reporting systems began to enter the marketplace.

“Vendors tried to make these systems be all things to all people, myself included,” he explained. “We spent lots of time, money, and energy and designed some good systems, but the end result was frequently not intuitive, nor was it simple to use in the typical doctor’s office environment. As a result, the physicians did not accept these systems and use them as quickly as we hoped.

“Many of the current vendors of lab test reporting systems have less ambitious goals,” stated Fishkin. “They incorporate the lessons of the past few years and stress basic functions which more closely emulate the workflow and needs of physicians and their staffs. **TDR**

Contact Cory Fishkin at 845-267-4385 or email: cfishkin@optonline.net.

New Competitors Vie for Business

Analysis of Lab Testing Market Reveals Competitive Shifts

SPECIAL INTELLIGENCE BRIEFING

BY ROBERT L. MICHEL

DURING THE PAST SIX YEARS, fundamental shifts occurred in the marketplace for both clinical laboratory testing and anatomic pathology services.

These marketplace shifts evolved at a steady pace between 1995 and the present, often escaping the conscious notice of many lab executives and pathologists even as they intuitively repositioned their labs to respond to these changes.

There are new competitors, and new market dynamics, in both clinical lab testing and pathology services. These new forces are rooted in how and where test specimens originate. Before looking at the “new” market dynamics, it will be helpful to understand the basic size of the lab testing market and how it is calculated.

Attempting to estimate the size of the lab market places us on a murky road, however. It is one which is often marked by controversy and differences of opinion. The challenge is gathering accurate data on the volume of lab tests performed each year in the United States. As most lab executives and pathologists know, accurate and highly-reliable numbers do not

CEO SUMMARY: *Even as public lab and anatomic pathology companies enjoy sustained growth in specimen volumes and revenues, fundamental shifts in the basic marketplace have changed the competitive environment. Surprisingly, the most open market segment is anatomic pathology specimens referred by physicians’ offices. Hospital inpatient and outpatient testing continues to be a limited growth opportunity for commercial labs, while competition for routine testing from docs’ offices is increasingly between hospital lab outreach programs and the two national laboratories.*

exist. The range of payers, from private health insurers, Medicare, Medicaid, and patient self-pay, make it difficult to gather information and develop an aggregate number. Similarly, on the provider side, lab testing is done in tens of thousands of settings including stand-alone labs, hospitals, physicians’ offices, and in patients’ homes.

Varying Estimates

During the past decade, I have seen estimates for lab and pathology testing that range from about \$30 billion per year to as much as \$36 billion. Sources for these estimates include consultants, govern-

ment health planners, Wall Street analysts, and public lab companies.

There are two safe conclusions to make from this situation. First, on a consensus basis, experts looking at the laboratory services market seem to agree on a figure in the low to mid-\$30 billion range for the annual value of lab and pathology testing.

Second, it is common for someone to cobble together an estimate using an unknown methodology. This estimate then is picked up and quoted by any number of other sources. Thus, there is often a good amount of “honest-wrong”

information floating around—believed to be right for sincere reasons, but developed from unverifiable numbers.

Against this background, I think it is reasonable to accept a number in the mid-\$30 billion range for the total value of clinical laboratory testing and anatomic pathology services performed annually in the United States. To make the math simple, I will use \$36 billion for the annual income associated with clinical lab testing and anatomic pathology services.

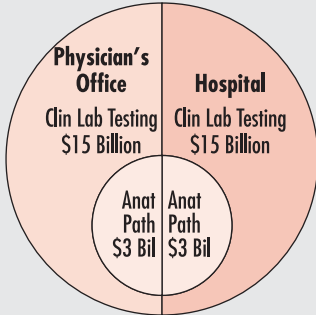
\$6 Billion For Anatomic Path

Of this number, probably \$6 billion can be attributed to anatomic pathology. Again, different experts offer different numbers. For example, it is known that the typical hospital-based pathologist will generate an average of about \$500,000 per year in collected revenues. There are more than 13,000 board-certified pathologists in the United States. Deduct a number for retired, semi-retired, researchers, and newly-minted doctors working in residency and internship programs, and a reasonable estimate is 12,000 pathologists. If these 12,000 generated an average of \$500,000 per year per pathologist, the aggregate total would be in the range of \$6 billion.

These numbers help frame the following analysis of competitive dynamics in

Chart 1: Total Testing Pie

Assume: \$36 billion per year
 Clinical Lab Testing = \$30 billion
 Anatomic Pathology Services = \$6 billion



This chart shows that approximately half of clinical lab testing and anatomic pathology originates from hospital inpatients & outpatients. The other half originates from physicians' offices.

the four segments of the lab testing industry. It is important to remember that these are ballpark estimates. The fudge factor on specific numbers can be significant, but won't affect the fundamental analysis which follows.

Chart 1 illustrates what we can call "Robert's Rule of 50/50." For all intents and purposes, about half of all testing originates in hospitals. The other half of testing originates in physicians' offices. This 50/50 ratio is a ballpark generalization. Obviously, any number of estimates out there give hospitals a market share ranging from 45% to 55% of all testing. But the basic point is unchallenged. Give or take a few percentage points, hospitals originate about half of all lab specimens.

"Robert's Rule of 50/50" defines four market segments which can be separately analyzed. They are: 1) hospital-originated clinical lab testing; 2) physicians' office-originated clinical lab testing; 3) hospital-originated anatomic pathology testing; and 4) physicians' office-originated anatomic pathology testing. Assessing each of these four testing segments helps

reveal the different competitors and new market dynamics that emerged since 1995.

testing segment

1

Hospital-Originated Clinical Lab Testing

Chart 2 shows how hospital-originated clinical laboratory testing comprises the largest single chunk of the testing marketplace. It totals about \$15 billion per year. This includes hospital inpatient and outpatient testing. It does not include physicians' office-originated testing which might be done by a hospital laboratory.

A relatively small slice of this market is done by non-hospital labs. Generally called "send-out" testing, it consists of the reference and esoteric tests that a hospital needs but does not do in-house. Thus, these tests are referred (or "sent-out") to a select number of reference labs.

Also, there are commercial lab/hospital lab joint ventures which involve the routine testing normally done within a typical hospital setting. However, these are relatively few in number and so only affect a small percentage of this market segment.

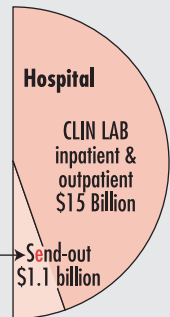
Chart 2: Hospital Clin Lab

Assume: \$15 billion per year

Hospitals strive to do as much of their own lab testing as possible. Send-out testing is the primary portion where outside labs can compete.

Estimates of "Send-out" Revenue

Quest	\$400 million
LabCorp	\$180 million
Specialty	\$148 million
ARUP	\$116 million
AML	\$ 90 million
Mayo	\$ 91 million
Esoterix	\$ 55 million



testing segment

2 Physicians' Office-Originated Clinical Lab Testing

As chart 3 reveals, this segment represents about \$15 billion in annual testing revenues. However, it's important to note that about half of this \$15 billion is done by physicians' office laboratories (POLs). These are test specimens which are done in-house.

That leaves \$7.5 billion of testing that can be done by commercial laboratories. Here is the market where there is intense competition between three classes of laboratories: 1) the two national labs (**Quest Diagnostics Incorporated** and **Laboratory Corporation of America**); 2) independent commercial laboratories (usually local or regional); and 3) hospital laboratory testing outreach programs.

What becomes obvious when looking at this \$7.5 billion slice is that Quest Diagnostics and LabCorp already hold \$4.37 billion of this market, or 58.3%. (This factors out an estimated portion of the two lab companies' revenues attributable to hospital send-out testing and anatomic pathology.)

For the remaining \$3.1 billion, the change since 1995 is that most of

this business is being done by hospital lab outreach programs. There are only a handful of independent commercial labs remaining in the United States, due to mergers, acquisitions, and bankruptcies throughout the 1990s.

Hospital lab outreach programs are a consequence of the growth in multi-hospital health systems since the mid-1990s. These lab outreach programs were created to serve the local medical office campuses surrounding the health system's hospitals. They fill the vacuum left after most local independent labs were acquired by larger lab companies.

testing segment

3 Hospital-Originated Anatomic Pathology

Hospitals originate at least half of all the anatomic pathology specimens, which, given my assumptions, totals about \$3 billion per year. This is illustrated in Chart 4.

Typically, this work is done by local pathology group practices. Because of consolidation, a growing proportion of these local pathology groups are serving more than one hospital in their local market.

Chart 3: Doc's Office Clin Lab

Assume: \$15 billion per year

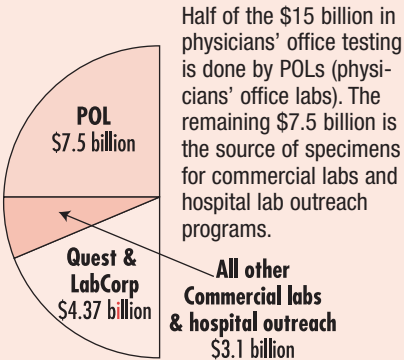
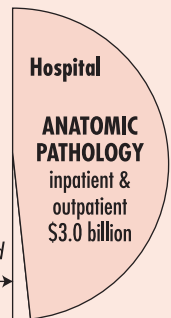


Chart 4: Hospital Anat. Path

Assume: \$3 billion per year

Currently the vast majority of hospital inpatient and outpatient AP is performed by local pathology groups. AmeriPath is the only company which has acquired enough hospital-based path groups to pick up measurable market share.

AmeriPath does an estimated \$200 million of hospital inpatient and outpatient AP



These specimens originate from hospital inpatients and outpatients, so only a small portion of this work is referred (sent-outTM) to other pathology labs. To participate in this market segment, a company would have to own the local pathology group which holds the anatomic pathology (AP) services contract with the local hospital.

Currently, only one public company fits this description. It is **AmeriPath, Inc.**, which owns both office-based dermatopathology practices and local hospital-based pathology groups. AmeriPath does an estimated \$200 million per year of hospital-originated anatomic pathology work.

testing segment

4 Physicians' Office-Originated Anatomic Pathology

Chart 5 shows this testing segment. Currently there is lots of competitive action in this \$3 billion segment. Historically, the primary providers to this market segment have been local pathology group practices.

However, during the past four or five years, companies like AmeriPath, **DIANON Systems**, **IMPATh**, **UroCor**, and others have launched extensive sales and marketing programs

into the physicians' office environment. These marketing efforts have fueled significant and sustained growth in specimen volumes and revenues.

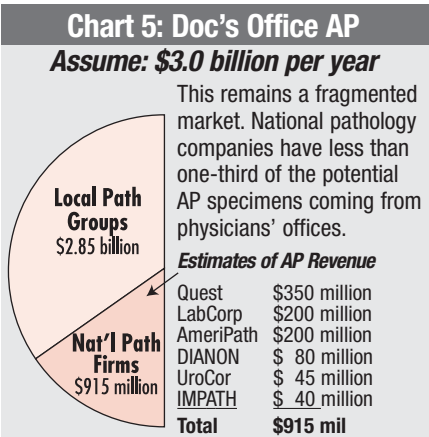
Quest Diagnostics and LabCorp also do considerable business in this segment. Estimates are that this totals about 10% of their annual revenues, or \$350 million and \$200 million, respectively.

Conclusions & Observations
 Breaking down the market for clinical lab testing and anatomic pathology in this manner allows us to isolate and identify the significant changes which occurred during the past ten years. It leads to some interesting conclusions and observations.

The physicians' office clin lab testing segment has probably seen the most significant changes. First, Quest Diagnostics and LabCorp now control almost 60% of the national market. Second, competition for these specimens increasingly comes from hospital lab outreach programs, not from regional independent commercial labs. Collectively, these two factors have changed the competitive dynamics in physicians' office testing.

It might also be argued, with justification, that the two blood brothers will have a difficult time increasing their share of this market segment. On one hand, much of the business they don't have may be in regions where they have minimal or no support infrastructure. On the other hand, in regions where they are strong, professionally-managed hospital lab outreach programs are successfully positioning themselves to be a high-service Avis ("We try harder") to the blood brother's Hertz ("We're number one").

Also undergoing significant change is the competitive market for anatomic pathology specimens generated by physicians' offices. Whereas this market was overwhelmingly served by



local pathology groups as recently as 1997, during the past four years a handful of national pathology companies have made major gains in market share, revenues, and profits. Having captured as much as 26% of this market, it appears these companies have plenty of room for continued growth in specimen volume and revenues.

Competing For Specimens

That means a mixed bag in competing for physicians' office business. For clinical laboratory specimens, competition will increasingly be between the two national labs and local hospital/hospital system lab outreach programs.

Moreover, in coming years the arrival of viable point-of-care testing instruments that allow the physicians to do more tests in-office and get paid for them will certainly change this market segment. It may reduce the flow of specimens (and associated revenues) sent to commercial labs and outreach test programs. On the other hand, a growing menu of POL tests may create an opportunity for labs to earn revenue by managing POLs for physician group practices.

Competition for anatomic pathology specimens originated by office-based physicians is thriving in the current market environment. There seems to be ample growth opportunities for national anatomic pathology providers. However, THE DARK REPORT predicts that, in many cities, local pathologists will consolidate into regional super-groups. This will give them both the capital base and specialized pathology expertise needed to successfully compete against the national AP companies.

Things are equally interesting on the hospital side. There seems to be little evidence to date that commercial labs have strong prospects for capturing sizeable shares of the market for

hospital inpatient and outpatient lab testing. Since the mid-1980s, almost every publicly-traded laboratory company has told Wall Street that it sees hospital lab testing as a fertile, untapped market. Yet, after 20 years of sustained marketing to hospitals, the current crop of public lab companies has just a limited number of situations where it participates in the routine testing of hospital inpatient/outpatient lab specimens.

THE DARK REPORT's prediction is for little change in this situation. Similarly, unless a well-financed company proves willing to buy local pathology practices, the majority of hospital-based anatomic pathology will continue to be done by local pathology groups. However, because of changing technology, these same local pathologists may be referring ever-increasing numbers of cases to national AP companies to do more sophisticated diagnoses.

Broad Estimates

Finally, a caveat and a disclaimer: As noted earlier, the numbers included in this assessment of laboratory market changes are broad estimates. In many cases, public companies do not break out and disclose revenues for certain lines of business, which makes it impossible to verify precise numbers.

Notwithstanding these facts, this intelligence briefing does provide a "big picture" view of the macro changes which have altered competitive dynamics within the clinical lab testing and anatomic pathology segments of the lab marketplace. These are the forces impelling changes in how clinical labs and pathology group practices organize and deliver lab testing services.

TDR

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Public Laboratory Rankings

General Reference Laboratories

Ranking By 2000 Annual Revenue (\$s in millions)

Rank	Laboratory	2000 Revenue	% Change	1999 Revenue
1.	Quest Diagnostics Incorporated	\$3,421	+55.1%	\$2,205
2.	Laboratory Corporation of America	\$1,919	+12.9%	\$1,699
3.	Dynacare, Inc. ¹	\$353	+29.3%	\$273
4.	LabOne, Inc.	\$169	+40.8%	\$120
5.	Bio-Reference Laboratories, Inc. ²	\$66	+22.2%	\$54
Total: General Reference Laboratories		\$5,928	+36.2%	\$4,351

1. Dynacare completed its public stock offering in November 2000.

2. BRL's fiscal year ends 10/31/01.

NOTE: Unilab Corporation was a private company in 2000.

Public Laboratory Companies Continue To Generate Strong Rates of Growth

CALENDAR 2000 was a banner year for all public laboratory and pathology companies in the United States. Virtually every company reported double-digit growth in annual revenues.

The new twist in the lab marketplace is the arrival of national lab companies offering anatomic pathology services. Their impressive financial

performance demonstrates that office-based physicians are willing to refer anatomic pathology specimens to out-of-town labs if they perceive the service to be better.

During 2001, the financial performance of public lab companies has continued along the trends established in 1999 and 2000.

Niche & Pathology Lab Companies

Ranking By 2000 Annual Revenue (\$s in millions)

Rank	Laboratory	2000 Revenue	% Change	1999 Revenue
1.	AmeriPath, Inc. (pathology management)	\$330.1	+28.4%	\$257.4
2.	Specialty Labs ¹ (reference)	\$153.2	+17.7%	\$130.1
3.	IMPATH Inc. (oncology)	\$138.2	+61.8%	\$85.4
4.	DIANON Systems, Inc. (pathology)	\$95.7	+25.7%	\$76.1
5.	UroCor, Inc. (urology)	\$52.6	+15.6%	\$45.5
6.	PharmChem, Inc. (substance abuse)	\$46.8	+5.4%	\$44.4
7.	MedTox (substance abuse)	\$42.8	+22.3%	\$35.0
Total: Niche & Path Lab Companies		\$859.4	+\$28.0%	\$673.9

1. Specialty Laboratories completed its public stock offering in November 2000.

Lab Industry Briefs

ROTARY CLUBS LAUNCH MEXICO-BASED CERVICAL SCREENING EFFORT

IN MEXICO, **Rotary International** will attack the problem of cervical cancer among Mexican women by supporting a screening program that utilizes human papillomavirus (HPV) testing.

Called "Test for Life," the program will be run by local Rotary clubs in Mexico and the United States. It is funded by a grant from the Rotary Foundation and targets women in urban and rural areas who are currently underserved by existing cervical cancer screening and treatment services. The program's first two clinics are expected to become operational this summer.

There are several intriguing aspects to this program. "Test for Life" will primarily use **Digene Corporation's** Hybrid Capture® 2 HPV DNA test, not conventional Pap smears, to screen for cervical cancer. Also, the **Cleveland Clinic Foundation** will use data generated by "Test For Life" as the basis for a clinical study.

One noteworthy feature of "Test For Life" is patient self-collection. Digene's Chairman and CEO, Evan Jones, stated that "an important aspect of this program is that it marks the first broad-based use of a self-collected cervical cancer screening test."

The "Test for Life" program in Mexico demonstrates how developers of new diagnostic technologies continue to look for clinical utility in countries where health services are less well-developed. Digene's efforts in Central America and Southern Africa have been reported earlier by THE DARK REPORT. (See TDR, January 24, 2000.)

This program also follows the strategic product launch example of **Cytec Corporation**. When it introduced its

ThinPrep® thin-layer Pap smear test, Cytec was careful to cultivate the support of women's health advocates. During various stages of the approval and acceptance process, women's health advocates played a valuable role in arguing for acceptance of thin-layer Pap smear testing by clinicians and payers. Digene would obviously like to gain that same kind of support, once it can demonstrate acceptable performance of its HPV test in the "Test For Life" program in Mexico.

IVAX DIAGNOSTICS BECOMES NEWEST PUBLIC INSTRUMENT VENDOR

WITHOUT MUCH FANFARE, the lab industry gained a new publicly-traded diagnostics company early this spring.

The "newborn" is **Ivax Diagnostics, Inc.**, based in Miami, Florida. It was formed by a merger of the diagnostic business subsidiary of **Ivax Corporation** and **b2bstores.com, Inc.**, an Internet-based company that decided there was more future in a "real" business like diagnostics.

Ivax Diagnostics had sales of \$11.8 million during 2000. Its three operating subsidiaries are: **Diamedix Corporation**, which manufactures diagnostic kits that can be run either manually or on its MAGO® instruments; **Immuno-Vision, Inc.**, which develops and manufactures autoimmune reagents and research products; and **Delta-Biologicals S.r.l.**, based in Parmezia, Italy, which developed and manufactures the MAGO instrument and sells its products to labs in Italy.

Under the leadership of President and CEO Giorio D'Urso, Ivax Diagnostics concentrates on the immunoassay market and offers a variety of test kits built upon

ELISA technology. Its Mago instrument is an automated solution that is designed to be “load and walk away.” Ivax intends to stay focused on specialty immunoassays.

MYRIAD GENETICS ANNOUNCES DEAL WITH EUROPEAN LABORATORY

IN ANOTHER EXAMPLE of an American-based diagnostics company doing business overseas, **Myriad Genetics, Inc.** announced a testing agreement with **Bioscientia Ltd.**, based in Ingelheim, Germany.

Bioscientia will collaborate with Myriad to offer its family of BRAC-Analysis[®] predictive tests in Germany, Switzerland, and Austria. Bioscientia is a large lab, capable of performing esoteric tests and handling more than 12 million tests annually.

Under terms of the agreement, Bioscientia will send test specimens for analysis to Myriad’s laboratory in Salt Lake City, Utah. Myriad will transfer “technical know-how for site-specific mutation detection to Bioscientia.”

LABONE SNAGGED IN LAWSUIT OVER DRUGS-OF-ABUSE TESTING

ON JULY 6, A PORTLAND, OREGON JURY tagged **LabOne, Inc.** with a \$400,000 compensatory damage award in favor of Yasuko Ishikawa, a **Delta Airlines** flight attendant.

It’s a case that demonstrates the slippery ground concerning certain aspects of drugs-of-abuse testing. Delta had terminated Ms. Ishikawa based on a **LabOne** report of “test not performed—specimen substituted.” The low creatinine in Ms. Ishikawa’s specimen triggered the report. Ms. Ishikawa has since been rehired by Delta.

LabOne was caught by implementation timetables for bureaucratic rul-

ings. **The Department of Health and Human Services** (DHHS) had issued Program Document 37 (PD) 37 on July 28, 1999 calling for labs to report creatinine results “to one decimal point beyond a whole number rather than to the whole number.” PD 37 did not specify an implementation date for laboratories to comply.

LabOne performed the test on Ms. Ishikawa’s specimen in September 1999, using the whole number reporting method. Like many other labs, it implemented the change to decimal point reporting required by PD 37 in January 2000. Ms. Ishikawa’s attorneys successfully argued that, had **LabOne** fully implemented PD 37 in September 1999, her sample would not have been reported as substituted.

AETNA STRUGGLES WITH LEAKAGE AND UNDERPRICED PREMIUMS

ALTHOUGH A NUMBER of big managed care companies are reporting improved finances, **Aetna, Inc.** continues to operate in the red.

The company has declined to provide earnings guidance for the balance of 2001, a sign of financial uncertainty. Most financial analysts are predicting that Aetna will again lose money in second quarter 2001.

One big issue is underpricing of insurance premiums. “They took their eye off the ball,” stated Oliver Marti, Portfolio Manager at **Columbus Circle Investors**. “As a result, they underpriced their business.”

Also, Aetna’s HMO medical cost ratio soared to 90% in the first quarter, compared to 85.9% in second quarter last year. To stem the outflow, Aetna is reviewing sources of leakage, increases in medical costs, how patients are using healthcare, and how medical claims are processed.

INTELLIGENCE

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



Chairman and CEO Mark Chandler recently disclosed that researchers within **Luminex Corporation** are developing new detection capabilities that would permit its LabMap system to “simultaneously perform a broad range of cellular, microbial, and related tests, such as complete blood counts (CBC) and bacterial analysis. The company recently filed an initial patent application covering aspects of this new technology.

MORE ON: LUMINEX

LabMAP is a multiplex bioassay testing system currently capable of doing 100 analytes on one specimen. (See *TDR, December 21, 1998*.) Chandler is apparently eyeing applications of Luminex technology for routine diagnostic testing, stating that “by performing some of the most common medical tests together in a single sample...these new detection capabilities would open up an additional \$8 billion of the current life science market for Luminex’s MAPing technology.”

TENET DECLARES AGING BABY BOOMERS NOW DRIVING HEALTH SERVICES DEMAND

Tenet Healthcare Corporation may be first to publicly declare that aging baby boomers are finally pushing up demand for healthcare services. The company reported a 33% jump in earnings per share for fiscal fourth quarter ending May 31, 2001. It attributes this strong performance to increased hospital admissions by baby boomers. During the quarter, admissions among patients in the 41-50 year-old cohort increased 8% and 10% among patients aged 51-60 years old.

ADD TO: TENET

Tenet’s recognition that aging baby boomers are beginning to drive up admissions rates is a good sign for the clinical laboratory industry. It means that, even as efforts to control test utilization become more widespread, population demographics may now be about to fuel a legitimate increase in the demand for lab testing. This bodes well for all classes of laboratory testing

providers. Further, Analyst Jeffrey Hoffman at **Buckingham Research Group** predicts the supply of hospital beds will shrink relative to demand. “...in many markets you no longer have this glut of beds, and in some markets capacity is actually expanding,” he said. It’s expected that stronger demand will allow hospitals to successfully negotiate higher prices from private payers and Medicare. This also would benefit the hospital-based labs.

APL HAS A NEW NAME

A respected name in the independent commercial laboratory industry is disappearing. **Associated Pathologists Laboratories (APL)** of Las Vegas, Nevada will drop its current name and begin operating as **American Medical Laboratories, Inc. (AML)** this month. AML acquired APL in 2000. Since the early 1970s, APL has been the dominant laboratory in both Las Vegas and Nevada and is generally recognized as having been one of the better-managed independent commercial labs in the country.

***That’s all the insider intelligence for this report.
 Look for the next briefing on Monday, August 13, 2001.***

THE **LAB** REPORT

UPCOMING...

- ***Six Sigma and Lean Manufacturing:
Powerful New Management Tools
for Driving Out Costs In Hospital Labs.***
- ***Web-Accessed Lab Reporting:
Deciphering Vendor's Pricing Plans
to Get the Best Deal.***
- ***Regional Lab Consolidation Enters
New Market Cycle.***