

Public Laboratory Rankings

2001 Another Year of Fast Growth!

Boom times continued during 2001 for both the clinical laboratory industry and anatomic pathology profession.

Throughout 2001, almost every public lab company was able to post double-digit revenue growth. For a number of companies, this growth was accomplished by acquiring smaller laboratory companies.

But most lab companies also report strong increases in specimen volume attributable to sales efforts. This is compelling evidence that investments in professional sales and marketing programs are worthwhile in today's health-care environment. Hospital outreach programs and local pathology groups should take note and develop their own effective sales program.

General Reference Laboratories Ranking By 2001 Annual Revenue (\$s in millions)

Rank	Laboratory	2001 Revenue	% Change	2000 Revenue
1.	Quest Diagnostics Incorporated ¹	\$3,627.7	+6.1%	\$3,421.2
2.	Laboratory Corporation of America	\$2,199.8	+14.6%	\$1,919.3
3.	Dynacare, Inc. ²	\$402.4	+14.0%	\$352.9
4.	Unilab Corp.	\$390.2	+15.6%	\$337.5
5.	American Medical Laboratories ³	\$297.0	+13.9%	\$260.8
6.	LabOne, Inc. ⁴	\$233.9	+38.0%	\$169.2
7.	Bio-Reference Laboratories, Inc. ⁵	\$81.6	+22.7%	\$66.3
Total: General Reference Laboratories		\$7,232.6	+10.8%	\$6,527.2

¹ Quest Diagnostics has an agreement to acquire Unilab in 2002.

² LabCorp has an agreement to acquire Dynacare in 2002.

³ Quest Diagnostics acquired American Medical Labs in 2002.

⁴ BRLI's fiscal year ends 10/31/01.

⁵ Majority of LabOne's revenues come from life insurance testing.

Niche & Pathology Lab Companies Ranking By 2001 Annual Revenue (\$s in millions)

Rank	Laboratory	2001 Revenue	% Change	2000 Revenue
1.	AmeriPath, Inc. (pathology management)	\$418.7	+26.8%	\$330.1
2.	IMPATH Inc. (oncology)	\$189.6	+37.2%	\$138.2
3.	Specialty Labs (reference)	\$175.2	+14.3%	\$153.2
4.	DIANON Systems, Inc. ¹ (anatomic pathology)	\$125.7	+31.3%	\$95.7
5.	PharmChem, Inc. ² (substance abuse)	\$43.9	-6.2%	\$46.8
6.	MedTox (substance abuse)	\$49.1	+14.5%	\$42.8
Total: Niche & Path Lab Companies		\$1,002.2	+24.1%	\$806.8

¹ DIANON acquired UroCor during 2001.

² PharmChem was delisted from NASDAQ in 2002.

Calif. Lab Regulators Are A Tough Bunch

Other public lab companies in Golden State have run afoul of state laboratory regulations

CEO SUMMARY: *By law, government regulators cannot comment publicly about the actions they take against the companies they regulate. That's why the lab industry never learned that other public lab companies operating in California, following inspections by state authorities, were judged to have some deficiencies similar to those found at Specialty Laboratories.*

BY NOW, JUST ABOUT EVERYONE in the lab industry knows that **Specialty Laboratories, Inc.** was hit by sanctions that included revocation of its CLIA-88 license, subject to an appeal which was filed by the troubled laboratory company last month. (*See TDR, April 22, 2002.*)

What most laboratorians don't know is that California laboratory regulators have been tough on several other well-known laboratory companies in past years. What was different in most of these earlier cases is that the public lab companies were able to keep news of regulatory deficiencies from becoming public knowledge.

Undisclosed Facts

THE DARK REPORT has tracked these fascinating stories over the years, since they provide insights into the enforcement philosophies of laboratory regulators. For example, back around 1989, **Nichols Institute**, then an independent public company, was inspected by the **California Department of Health Services** (CDHS). Deficien-

cies were deemed serious enough that Nichols Institute was required to develop an acceptable plan of correction (POC) and was subject to state inspections for a two-year period, ending around 1991. News of this situation was kept confidential and never became public knowledge.

Another situation occurred in the 1998-99 time period. CDHS lab regulators cited the Van Nuys laboratory owned by **SmithKline Beecham Clinical Laboratories** (SBCL) for deficiencies. This was prior to SBCL's acquisition by **Quest Diagnostics Incorporated**. SBCL ceased certain lines of testing at that facility and was forced to send those specimens to its lab in Dublin, California until the deficiencies in Van Nuys were corrected.

An even more interesting case involved **PharmChem, Inc.**, the drugs-of-abuse testing company. In recent years, while it was still based in Menlo Park, California, PharmChem was caught in the regulatory crosshairs of CDHS lab officials. Of the

deficiencies cited, some mirrored those at Nichols in 1989 and Specialty Labs in 2002, most notably the use of “unlicensed personnel” to perform and supervise testing.

Since a number of public lab companies have experienced similar episodes with California lab regulators, Specialty Lab’s case is exceptional specifically because sanctions reached the point of license revocation.

As with other labs cited by CDHS inspectors, PharmChem had Ph.D.s, some with board certifications in diagnostic specialties, working in the lab, but not holding a license as a clinical laboratory scientist (CLS) under California regulations. Since these Ph.D.s lacked the CLS license, CDHS regulators found the lab to be in violation of state regs requiring CLS-licensed individuals “to perform and supervise” testing.

One unique feature of PharmChem’s dispute with its regulators involved the interpretation of state lab regulations covering “patients.” Unlike earlier years, CDHS regulators began defining the individual who provided a drugs-of-abuse test specimen as a patient. Based on this new interpretation, CDHS then cited PharmChem for deficiencies under regulations intended to address clinical laboratory testing, despite the company’s activities in drugs-of-abuse testing.

Legislative Branch Appeal

Executives at the laboratory tell THE DARK REPORT that the situation escalated to the point where regulators actually drafted a “cease and desist.” To resolve the issue, this laboratory company went

to the state legislature, pled its case, and gained relief through passage of legislation clearly defining the differences for regulating clinical laboratory testing as distinct from drugs-of-abuse testing. In recent years, this lab company relocated its testing activities outside the state of California.

THE DARK REPORT has been told that the same regulators involved in this case are also involved in the Specialty Laboratories case. As noted above, THE DARK REPORT has documented serious regulatory actions between the California Department of Health Services and Nichols Institute, SBCL, PharmChem, and, most recently, Specialty Laboratories.

Each was a public lab company at the time that regulators identified deficiencies during inspections. Taken collectively, this is factual evidence that, at some level, the fundamental relationship between certain lab companies in the state and CDHS lab enforcers is probably not amicable.

Little Information Available

Since a number of public lab companies have experienced similar episodes with California lab regulators, Specialty Lab’s case is exceptional specifically because sanctions reached the point of license revocation. The differences are difficult to judge, since few details about the deficiencies have been disclosed by either lab regulators or Specialty Laboratories.

But each of these earlier cases does support a conclusion that aspects of California’s lab regulatory environment have become unwieldy. Changes in laboratory technology, such as molecular and genetic diagnostics, and the growing shortage of technically-trained laboratorians, may have outmoded existing regulations which were created years ago to address a different set of problems.

INTELLIGENCE

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



Guess whose DNA was used by **Celera Genomics** during its project to map the human genome back in 1999? It was primarily the DNA of J. Craig Venter, Ph.D., who was Chairman of Celera at that time. The disclosure, made last week, has stirred some controversy. Defenders say it is in the tradition of self-experimentation by researchers. But critics say it was motivated by Dr. Venter's desire to immortalize himself. At any rate, the disclosure now lets laboratorians involved in genomic research know the source of the human DNA with which they work.

DIANON POSTS STRONG GROWTH

DIANON System, Inc.'s acquisition of **UroCor, Inc.** last year is paying off. The anatomic pathology company reported an increase of 66% in revenues for the quarter, from \$26.8 million in Q1 2001 to \$44.6 million for Q1 2002. Net income increased by 128% for the quarter.

FIRST "ID CHIPS" IMPLANTED IN HUMANS

Last week, doctors in Florida implanted "ID chips" into several humans. When a handheld scanner is waved over the chip, it emits a signal with an ID number. This number, when entered into the Web site of the manufacturer, **Applied Digital Solutions, Inc.**, allows the user to obtain medical or other information about the individual carrying the chip. The goal is to eventually provide medical histories and information about the individuals carrying the chips. The technology is similar to that used by pet ID chips. One barrier to use is that hospitals and physicians do not have the scanners, which cost at least \$1,000. Since lab data is a major part of most medical records, laboratorians should keep an eye on this developing technology.

ADD TO: ID Chips

Here's another example of how implanted instruments in humans can generate diagnostic data. **Biotronik** has developed a pacemaker that includes a computer chip

which tracks heart rhythm and the number of jolts delivered. Ordinarily the physician must see the patient to evaluate the effectiveness of the pacemaker. But Biotronik's model links to a transmitter the patient keeps nearby. This connects to Biotronik and downloads the performance details of the pacemaker. Biotronik then sends a fax with this information to the physician. This type of technology may demonstrate the feasibility of in vitro diagnostic monitoring.

Beckman Coulter Reports Earnings

For the first quarter, **Beckman Coulter Corp.** posted revenue growth of 3.9% and earnings growth of 20%. Its clinical diagnostics business increased by 3.9% for the first quarter, totaling \$313.9 million versus \$302.1 million for first quarter 2001. Fastest-growing products were in robotic automation and genetic analysis, which grew 20%, and immunodiagnostics, which increased by 8%.

*That's all the insider intelligence for this report.
Look for the next briefing on Monday, June 3, 2002.*



UPCOMING...

- ***First Reports From the Executive War College: New Directions for Hospital Labs.***
- ***Pathology Billing and Coding: Fixing the Ten Most Common Errors.***
- ***What's Up with the Web? How Mergers Are Changing Browser-based Lab Services.***

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