

LABORATORY INDUSTRY REPORT®

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HIGHLIGHTS

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- New Year's Outlook For Lab Industry
- Exclusive interviews with:
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 - ★ Tom Mac Mahon LabCorp
 - ★ Joseph Sonnier, M.D. AmeriPath
 - ★ Robert DeCresce, M.D. Rush Presbyterian
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Top Laboratory Execs Preview Prospects For 2005

For an inside look at what may be in store for the lab industry this year, *Laboratory Industry Report (LIR)* interviewed the top executives at 10 leading commercial and hospital labs around the country. We begin with Surya Mohapatra, Ph.D., who recently became chairman of Quest Diagnostics (Teterboro, NJ), in addition to serving as chief executive.



Surya Mohapatra, Ph.D.

Mohapatra says that after completing a turnaround phase in the mid-to-late 1990s and then the merger and acquisition period of the past five years, Quest has now entered a growth phase with a focus on “organic” growth. Although Quest still has its eye out for potential acquisitions, Mohapatra says, “You can’t grow your family by buying other kids from the neighborhood.” He notes that Quest reviewed a number of acquisition opportunities in 2004 and passed on them all, often because the asking prices were too high.

Mohapatra sees anatomic pathology as a key growth market for Quest, especially second consultations and advanced cancer diagnostics. He says Quest, which employs more than 200 pathologists, is seeking ways to standardize its processes for collecting, transporting, testing, and reporting biopsies. New initiatives include the internal development of a new kit for transporting tissue samples. Quest is also rolling out an electronic test reporting system for cancer diagnostics that will combine numerical results with tissue images that can be manipulated by the viewing physician. ➔ pp. 5-11.

The Trials And Tribulations Of Two Lab Entrepreneurs

In November 2003, *LIR* published an article (“Who’s Crazy Enough To Start Their Own Lab?”) detailing the efforts of two medical technologists who had each started independent labs. Fast forward 13 months, and how are they doing? The good news is both Ken Shaffer, owner of **The Lab at Steamboat LLC** (Steamboat Springs, CO), and Sheela Puthumana, owner of **Clinical Diagnostics Labs** (Atlanta, GA—formerly named Diagnostyx Labs), have survived the toughest part of starting a new company—the first year. Although both entrepreneurs have suffered setbacks, each tells *LIR* that they are growing more and more confident in their ability to succeed. ➔ p. 2



■ TWO LAB ENTREPRENEURS, from page 1

Sheela Puthumana says her darkest moment came a few months ago when her three initial owner/partners discovered the lab business wasn't "a lemonade stand where you could make money overnight" and bailed out on her. However, she says her husband has jumped in with financial support, and she's now the sole proprietor of Clinical Diagnostics Labs, which has four employees, including one lab technician, a phlebotomist, office manager, and herself.

Puthumana says her lab is currently testing more than 30 patient specimens per day, but not yet operating at breakeven. Most of her clients are local nursing homes, home healthcare companies, small independent labs, and uninsured people. Puthumana adds that there is no advertising budget, other than having her lab listed in the *Yellow Pages*. "People are finding me from the phone book. I have the feeling that once I begin marketing it, my lab will take off," she says.

One of her biggest frustrations has been an inability to break into physician office testing. "I get phone calls from patients every day who want to be tested here, but can't because their managed care plan forces them to use a big lab," she says. Other ups and downs have included the purchase of a \$6,000 sign to place in front of her lab that turned out to be the wrong size, according to zoning regulations. And, of course, learning the ropes with billing Medicare and Medicaid has been a challenge.

So, if she had the chance, would she do it all over again? "Definitely. It's better than working under someone else. I like running my lab in a very particular way, and the lure of someday making money keeps me going," answers Puthumana.

Ken Shaffer says his lab still has only one employee, himself. "I draw blood, run the tests, and mop the floor," he says. The Lab at Steamboat is currently performing between five and 10 tests per day and operating slightly above breakeven. "For a startup business, I think I'm doing pretty well," says Shaffer.

"In the beginning, I chased doctor's offices for business, but all I got was the runaround.... I then realized I'd either have to find a niche, or close shop," says Shaffer. The niche has turned out to be direct testing to self-paying patients with high deductibles or no insurance.

"At first I ran soft-touch ads in the local newspaper, but that didn't work. Now my ads read, 'Lab costs making you sick? We provide quality lab work for a fraction of what other local labs charge.'" Shaffer says he places the ads along with his photograph in the help wanted section of his local newspaper. Help wanted ads are cheaper than regular newspaper advertising, and his picture helps because he's fairly well known in the small community of Steamboat Springs. This form of advertising has worked best, he says. His most popular test is a lipid panel priced at \$25.

If he could, would he do it all over again? "I wish I had done it earlier. There are no office politics, and nobody ever tells me, 'I can't do that. It's not in my job description.' It's been tough financially, but the pendulum is starting to swing the other way.... The best part is I've gotten to meet a lot of other entrepreneurs in other businesses that have the same basic struggles and issues. It's a much more optimistic group of people than you'll find at a hospital," answers Shaffer. 🏠

Puthumana and Shaffer each risked a lot of time and money to get their labs through the first year, but it looks like their entrepreneurial spirit and hard work is going to pay off.



LabCorp To Buy US Labs For \$155 Million

LabCorp (Burlington, NC) has agreed to buy US Labs (Irvine, CA) for \$155 million in cash. The deal is expected to close in February. The purchase price is equal to approximately two times US Labs' annual revenue of about \$75 million. LabCorp plans to keep US Labs as a wholly owned subsidiary, and Judd Jessup will stay on board as president.

US Labs was initially formed in 1997 to acquire and manage pathology groups, but in 2000/2001 it switched to providing cancer diagnostics to small hospitals and pathology groups. The company now has 430 employees and manages a single large anatomic pathology lab in southern California. US Labs generated

approximately \$75 million of revenue in 2004, up 39% from \$53.9 million in 2003. The company is owned by a group of venture capital firms that includes ABS Capital Partners (Baltimore, MD) and Highland Capital Partners (Boston, MA). ▲

Date	Buyer	Target	Purchase Price*	Acquired Revenue	Price/Revenue
Jan-03	LabCorp	Dianon	\$605.0	\$188.0	3.22
Mar-03	Welsh Carson	AmeriPath	800.0	479.0	1.67
Feb-04	Genzyme Genetics	Alfigen	47.6	20.0	2.38
Mar-04	LabCorp	Redding Pathologists	NA	NA	NA
May-04	Genzyme Genetics	Impath	215.0	125.0	1.72
Pending	LabCorp	US Labs	155.0	75.0	2.07

*Purchase prices include assumed debt; NA=not available Source: Lab Industry Strategic Outlook 2005

Chromosomal Labs Targets Fast-Growing DNA Testing Markets

Chromosomal Laboratories, a new independent lab company, has opened a 7,000 square-foot laboratory in Phoenix that will focus on forensic testing for criminal cases, DNA-based paternity testing, and possibly genetic testing for the clinical market. Paul Cochrane, vice president of business development, tells *LIR* that the formation of Chromosomal Labs comes at an ideal time to assist with the large backlog of DNA samples currently found in most state and federal crime labs.

For example, in a report commissioned by the U.S. Department of Justice (*National Forensic DNA Study Report*, Dec. 12, 2003), the total number of crime cases with possible biological evidence either still in the possession of local law enforcement or backlogged at forensic laboratories was estimated to be over one-half million (542,700).

Under President Bush's DNA Initiative, the Federal government has indicated its intent to allocate \$900 million between 2005 and 2009 toward reducing the backlog of forensic testing that currently exists in the criminal justice system. Through a process directed by the National Institute of Justice (NIJ) states may apply for federal funds to assist in testing the enormous backlog of untested cases. A substantial portion of the awarded funds are designated for outsourcing to private sector laboratories, which charge an average of more than \$1,000 per sample tested in forensic cases.

The largest privately held forensics DNA testing labs in the United States include Bode Technology Group, Commonwealth Biotechnologies, DNAPrint Genomics, Fairfax Identity Laboratories, Identigene, LabCorp, Myriad Genetics, Orchid Cellmark, and Reliagene.

Chromosomal Labs has also targeted DNA-based paternity testing, a \$100 million market that is growing by roughly 10% per year, according to estimates by *LIR*. About 90% of paternity tests are ordered by state child support enforcement agencies. Each paternity test requires blood or saliva samples from the mother, child, and alleged father; reimbursement averages between \$150 and \$200 per complete test. Competitors in the field of paternity DNA testing include DNA Diagnostics, Identigene, LabCorp, Long Beach Genetics, Orchid GeneScreen, Paternity Testing Corporation, and Reliagene.

Finally, Cochrane says Chromosomal Labs is in the process of getting a CLIA certificate and is considering opportunities to enter the clinical market for genetic testing.

Chromosomal Labs' founder and chief executive, Vladimir Bolin, was formerly head of Aerotech Laboratories (Phoenix), an environmental lab specializing in indoor air quality testing. Bolin founded Aerotech in 1993 and grew it to a 330-employee company with annual revenue of more than \$30 million. In March 2004, Aerotech was acquired by the Severn Trent Laboratories (Ft. Washington, PA), a \$300 million per year environmental testing company owned by the Severn Trent Group (Birmingham, England). 🏠

Exact Sciences Starts Consumer Advertising Campaign

The ads describe PreGen-Plus as "The new non-invasive DNA test that makes it easy to screen for colon cancer early" and tell people to ask their doctor about the test or contact LabCorp by phone.

In an effort to stimulate demand, Exact Sciences (Marlborough, MA) has begun direct-to-consumer marketing campaigns in the Fort Meyers area of Florida and in Greensboro, North Carolina, for the PreGen-Plus DNA test for colorectal cancer. Amy Hedison, spokeswoman for Exact Sciences, which developed PreGen-Plus, says the company will review the advertising results in the two test markets before possibly rolling them out to additional cities. Hedison would not disclose the budget for the two advertising campaigns.

PreGen-Plus is a \$795 test that detects DNA abnormalities linked to colon cancer. LabCorp is the exclusive North American licensee for the test, which was introduced as a homebrew test in late 2003. PreGen-Plus requires a complete bowel movement sample from the patient. The sample is mailed to LabCorp in a container, and results are sent to the patient's doctor two to three weeks later. If colon cancer is detected, patients must have a colonoscopy for confirmation. Based on its studies, Exact says PreGen-Plus has a sensitivity of about 65% and gives false positives 5% of the time. In the nine months ended Sept. 30, 2004, about 3,300 PreGen-Plus tests were performed.

The first ads ran on morning TV and local newspapers in Fort Myers from June to September 2004, but Hedison says the results could not be accurately gauged because of the unprecedented four hurricanes that swept through Florida last summer. The ad campaign in North Carolina began in September and will run through February. 🏠

Inside The Lab Industry: New Year's Special

Quest is eyeing international expansion and a move into diagnostic imaging as potential avenues for long-term growth, according to CEO Mohapatra.

Quest's Surya Mohapatra, Ph.D., says gaining Web-based connectivity to Quest's physician office clients is also a key strategy. "We are installing quite a lot of systems every week and winning new clients because of this," he says. Currently, Quest receives 40% of its test orders and provides 50% of test results via electronic connections, according to Mohapatra. He believes that one of the reasons physicians have been slow to adopt Web-based technologies is simple inertia. He also notes a certain level of skepticism on the part of physicians—some are worried that their test results will get lost in the Internet, and others lack confidence in the viability of some information technology vendors.

Mohapatra says Quest bought its own information technology company (MedPlus acquired in late 2001) so that it could "close the loop" with its patients and physician clients. "We want to collect the sample, transport the sample, run the tests, and report the results," he says. He notes that Quest added 1,000 phlebotomists over the past year to work at its patient service centers and directly at physician offices as part of the company's closed-loop strategy.

Quest's esoteric testing business is currently generating about \$925 million in annual revenue, including \$600 million from gene-based testing, and is growing at more than 10% per year, according to Mohapatra. Among Quest's fastest-growing tests are DNA-based HPV testing, cystic fibrosis genetic analysis, Chlamydia/gonorrhea, and ImmunoCap (an allergy test).

Mohapatra says that Quest will continue to seek licensing deals for new testing technologies. "We want to get a two- to three-year advantage for new tests and are getting involved in licensing at an earlier stage. We want to help bring new tests to market quicker, but we're not going to pay a lot for [long-term] exclusivity. He cites CellSearch, a test for identifying and counting circulating tumor cells in blood samples from metastatic breast cancer patients, as an example. "We brought this test to market just one month after the New England Journal of Medicine [NEJM—351; 781-791, Aug. 19, 2004] published study results on it," he notes.

Mohapatra says that Quest's total revenue grew by roughly 8% in 2004, with growth of about 1.5% contributed by Unilab (acquired February 28, 2003). As for Quest's 4.5% bad-debt rate, he says, "There's still room for improvement. We think we can get it below 4%."

Mohapatra says that Quest is exploring the possibility of getting into the diagnostic imaging business. "It's not a question of 'if,' it's a question of time... That's why we named the company Quest Diagnostics," says Mohapatra. In the future, he believes there will be a convergence of lab testing, genetic testing, and diagnostic imaging reports.

Finally, Mohapatra says Quest, which already owns labs in Mexico, Puerto Rico, and England, has begun looking at other international markets for growth. "There are 300 million people in the United States and six billion in the world," he notes. In particular, Mohapatra says Quest is looking at opportunities to expand in South America, Central Europe, India, China, and East Asia.



Thomas Mac Mahon

Tom Mac Mahon, chairman and chief executive of **LabCorp** (Burlington, NC), says the acquisition of US Labs (see page 3) will bolster LabCorp's cancer-testing presence on the west coast. He

says that with approximately 70,000 square feet of space in southern California, US Labs has plenty of capacity to add volume. LabCorp plans to expand US Labs' menu—now focused on lymphoma, leukemia, and breast cancer, to include additional molecular diagnostics and esoteric tests.

"The multiple we paid for USL is no different than the prices paid for labs in 2001 and 2002," notes Mac Mahon. He believes that acquisitions continue to be a better use of LabCorp's cash flow than share repurchases or a dividend. He anticipates additional acquisition opportunities for medium and small-sized labs in 2005.

Mac Mahon says that LabCorp currently receives a small percentage of its lab test orders via Web-based methods. "Doctors aren't that interested in switching to the Internet because we've made it so easy for them to send orders by paper and receive results by in-office printers," says Mac Mahon. "The shift to the Internet will continue to be gradual," he adds.

LabCorp's fast-growing test in 2004 was DNA-based HPV; other fast-growers included cystic fibrosis and anatomic pathology, according to Mac Mahon. "We expect PreGen-Plus (see page 4) to do better next year," he says. The drivers of demand for PreGen-Plus will include potential publication of study results in a medical journal sometime in 2005. He says LabCorp is also hopeful that Correlogic will resolve its issues with the FDA sometime soon,

allowing it to bring to market an ovarian cancer test that utilizes protein pattern recognition technology. [Note: Quest and LabCorp have exclusive distribution rights for this test in the United States.]

In terms of lab test pricing, LabCorp is receiving modest increases from managed care plans, which are focusing more and more attention on reducing leakage to out-of-network labs, according to Mac Mahon. Pricing for client billing to physician offices is also increasing a little, he says. However, pricing for reference testing services provided to hospitals has become very competitive. "There's a lot more competition. I'm not optimistic about [the pricing for] hospitals," he adds.

Mac Mahon believes getting appropriate reimbursement will continue to be the biggest challenge for the lab industry over the next few years. He says the competitive bidding plan for Florida Medicaid (see page 12) is "a very severe and negative issue." He also cites CMS's movement toward competitive bidding as a concern and believes the lab co-pay issue could arise again when congress refocuses its attention on budget issues after the holidays.

Meanwhile, Mac Mahon says that while LabCorp may have had cursory talks with the utilization management firm HealthHelp (Houston) about providing lab services directly to the major automobile manufacturers, no formal agreements were ever made and LabCorp has no intention of direct contracting with auto firms.

Mac Mahon, age 57, has been chief executive of LabCorp since January 1997 and *LIR* asked him how much longer he planned to run the company. "I have no plans to leave, although I spend a considerable amount of time discussing succession planning with the board," he answered.



Joseph Sonnier, MD

Joseph Sonnier, M.D., president of **AmeriPath** (Riviera Beach, FL), says AmeriPath is working to strengthen the relationship with the 400 pathologists it employs throughout the country. Among the changes: 1)

adding two physicians to the board of directors; 2) enhancing internal communications to pathologists/physicians; 3) reinstating the company's national physician meeting after a two-year lapse; 4) instituting a best-practices program to share ideas between pathology groups; and 5) creating a method to clarify and resolve conflicts between pathology groups located in the same market. Sonnier says the changes have been driven by AmeriPath's new chief executive, Donald Steen, who joined the company last summer.

In the nine months ended Sept. 30, 2004, AmeriPath reported revenue of \$378.8 million, up 5% from a year earlier. Sonnier says that esoteric testing revenue at the company's Center for Advanced Diagnostics (Orlando, FL) and other esoteric testing sites (Indianapolis, Dallas, and Denver) is growing by 10% to 12% per year and now represents about 9% of overall revenue. Among the fastest-growing tests are DNA-based HPV and Chlamydia/gonorrhea. He says that AmeriPath is in the process of building additional esoteric testing labs in Shelton, Connecticut, and Phoenix, Arizona.

AmeriPath made two acquisitions in late 2004, including St. Luke's Pathology Associates (Kansas City, MO), a four-pathologist group associated with the St. Luke's Hospital System, and Pathology Associates, P.C. (New Rochelle, NY), a group of seven pathologists that operate an independent lab focused on dermatopathology.

In the first nine months of 2004, AmeriPath's days in accounts receivable averaged 58 days with bad-debt expense of 15.4%. Sonnier says AmeriPath is working to improve its billing and collection systems by upgrading its information technology and raising the quality of employees in its billing department. He says the biggest challenge continues to be getting reimbursed by managed care companies for professional services provided by hospital lab medical directors.

Sonnier notes that a lawsuit concerning pathologists' ability to bill patients for professional component charges related to lab director services that are not reimbursed by health plans (Central States Southeast & Southwest vs. the Florida Society of Pathologists, AmeriPath, and Ruffolo, Hooper & Associates—see *LIR*, August 2002, pp. 1-3) was recently resolved. The final judgment allows pathologists to bill patients directly for professional services, but requires enhanced notification to patients when they register at hospitals.

AmeriPath was taken private by the investment firm Welsh Cason (New York City) in an \$800 million transaction in March 2003. Sonnier says the next most likely step is for AmeriPath to return as a publicly traded company through an IPO sometime in the next three to five years.



Ron Weiss, MD

Ron Weiss, M.D., president and chief operating officer of **ARUP Laboratories** (Salt Lake City, UT), says the biggest challenge labs could face in the next few years might be dealing with emerging infectious diseases and widespread outbreaks.

Weiss says the H5N1 virus that causes bird flu in Asia may pose the biggest risk for the

next pandemic. Last year 44 people were infected with the virus, 33 of them died. He says the fact that this virus has the ability to infect humans and is highly contagious makes it dangerous. "Labs have got to be prepared to deal with this because it's easy to imagine someone that's incubating influenza getting on an airplane and coming over here," he warns.

Meanwhile, Weiss says that ARUP increased its revenue by 14% in the fiscal year ended June 30, 2004, to reach \$217 million. He anticipates 10% to 15% growth this year as well. New tests recently added to ARUP's menu include: 1) a supplemental newborn screening panel by tandem mass spectrometry (TMS), which identifies an additional 30 metabolic disorders not detected by the state-required screens performed in some states; 2) a quantitative RT-PCR assay for patients with the Philadelphia chromosome translocation that causes chronic myelogenous leukemia; 3) a highly sensitive assay for free testosterone by TMS, especially for detecting levels in women and children, and 4) using TMS to determine levels of Everolimus (a new immunosuppressant drug made by Novartis) in transplant patients.

In terms of pricing for send-out tests, Weiss says the market has gotten more competitive over the past year. "GPOs are fostering pricing pressure. Many hospitals view GPOs as important mediators for contracts for medical supplies, and unfortunately reference lab services get lumped into it," says Weiss.

ARUP, which is owned by the University of Utah, operates a single large lab in Salt Lake City. "We have considered opening a second lab, but found that one facility minimizes the problem of multiple specimen handoff points. It's easier to keep track of specimens and maintain quality," says Weiss.



Robert DeCresce, MD

Robert DeCresce, M.D., chairman of pathology at **Rush Presbyterian-St. Luke's Medical Center** (Chicago, IL), which has 266 lab FTEs and performs 1.8 million billable tests per year, says Rush has moved from a focus

on high-volume, low-margin outreach testing to low-volume, high-margin genetic and cytogenetic testing.

Several years ago, Rush scaled back its routine outreach business to just its on-campus physicians, says DeCresce. He says hassles with billing and collection plus the loss of a big capitated contract led Rush to its new strategic direction. What's the biggest mistake he sees other hospital outreach programs making? "They think outreach is only about producing test results and fail to understand the customer service aspect," he answers. "It's like the auto business, which is more than just making cars. Marketing and long-term service are equally important," he adds.

DeCresce says the molecular diagnostics program at Rush currently generates about \$1 million per year in collected revenue, mostly from hospital clients. The lab at Rush handles the technical component, and University Pathologists, a 20-pathologist group affiliated with Rush, performs professional services. Areas of expertise include renal pathology, neuropathology, and dermatopathology. New tests that will be added to the menu in 2005 include Factor V Leiden, HCV, Herpes, HSV, and VZV by molecular technologies.

DeCresce says Rush is in the process of installing an automated hematology system from Sysmex. Rush is also looking at Web-connectivity systems. The challenge here is finding a system that can combine lab tests,

X-rays, prescription drug information, etc. to form a complete medical record for physicians to access.

What's the biggest change coming to the lab industry over the next few years? "There'll be more specialized tests coming to the market with the hope of getting high margins. But for many new tests, labs will be faced with demand, but not necessarily reimbursement," answers DeCresce.

Regarding the prospects for microarrays, De Crease says, "The question is who is going to pay for them? If they were priced at \$28 to \$42 per test, then gazillions would be sold. But at a few hundred dollars per test, payers are really going to be asking how essential the test information is to patient therapy. Unless a test leads to a yes or no answer on a clinical decision, it's unlikely to get reimbursed."

David Schultz, president of **Clinical Pathology Laboratories (CPL-Austin, TX)**, says CPL grew by 15% to 16% in 2004 to reach approximately \$170 million of revenue. "We are an alternative to the two big guys....Our philosophy is that lab services are provided by people, and we emphasize the personal touch. The big labs are focused on national contracts that limit physician choice. We sell ourselves based on better service and look for ways to get around those contracts," he says.

"I think there'll be more independent labs being formed. I think some former lab executives and marketing people from AML and other acquired labs see the two big guys dominating and see opportunities to create another choice in some markets," observes Schultz.

What about hospital outreach programs? "Some are opening up, some are closing, and this has been going on for years. However, there are some hospitals that

have gained a better understanding that outreach doesn't function well in the hospital environment, and they are moving to separate locations," answers Schultz.

In terms of pricing competition, Schultz says he's seen a little more downward pressure on managed care fee schedules. "Quest has been more aggressive in direct billing than we've seen in the past, while LabCorp continues to be aggressive," he adds.

What's in store for CPL: an IPO, selling to Quest, selling to LabCorp? asks *LIR*. "All of those things are options, but nothing is imminent," replies Schultz. CPL is owned by its pathologist founders, including its chairman Robert Connor, M.D., management, and the venture capital firm Summit Partners.



Larry Siedlick

Larry Siedlick, chief executive of **Sunrise Medical Laboratories (Hauppauge, NY)**, says some of the largest managed care companies, like Aetna and Cigna, have become a little more willing to talk

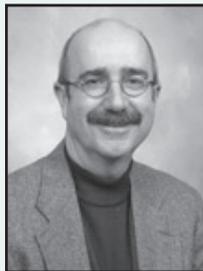
with Sunrise about the possibility of becoming an in-network lab provider. "The two national labs have gotten so big. They are approaching managed care companies with the attitude, 'You can't do business without us.'"

Sunrise is headquartered in Hauppauge, Long Island, approximately 30 miles east of New York City. In 2004, Sunrise, which has 285 FTEs, increased its revenue by 11% to \$46 million, including roughly 6% from increased volume and 5% from higher prices associated with more esoteric testing. Siedlick says volumes are growing fastest for cystic fibrosis genetic analysis and Chlamydia/gonorrhea testing.

Siedlick says that Sunrise, which uses Atlas, now receives nearly 50% of its lab test orders via the Internet. "It's labor intensive. You can't just put systems out there and walk away. It takes continual training because of the high turnover at physician offices," he notes. But he says the cleaner billing records from Internet orders have allowed Sunrise to lower its days in accounts receivable to 44 days.

What's your attitude toward hospital outreach? "Hospitals don't recognize the need to incentivise management properly so they go that extra mile when something goes wrong. How you deal with problems is what keeps customers," says Siedlick.

What's the biggest challenge for labs in the future? "You've got to control the expense side of your business because there's little you can do to control pricing," answers Siedlick. Right now, he says lab test pricing in the New York City area is about flat. "But I'm guessing there'll be downward pressure. HMOs are under pressure to grow profits, and I have this nagging feeling that the Medicare competitive bidding project could be used to justify reducing the lab fee schedule," he adds.



Ran Whitehead

Ran Whitehead, chief executive of **Oregon Medical Laboratories** (OML-Eugene, OR), says OML is planning to move into a new 67,000 square-foot laboratory in about one year. He says OML has outgrown its current 40,000 square-foot facility. The new space is located at a shuttered Sony compact disc plant in Springfield, Oregon, that has been purchased by OML's parent PeaceHealth (Bellevue, OR).

Whitehead says OML is in the final stages of making a decision on front-end automa-

tion and chemistry/immunoassay systems for the new lab. He estimates the total cost of renovating and equipping the new lab will be roughly \$9 million to \$10 million.

OML, which has 400 employees, grew its revenue by approximately 14% to reach \$45.5 million in the fiscal year ended June 30, 2004. Whitehead says OML is on track for another double-digit increase this fiscal year. An expansion north into the Portland and Vancouver markets that was initiated two years ago is helping to maintain growth.

This summer, OML will have four of its lab technicians graduate from an MT program they take online from the Medical College of Georgia. Under the two-year program, OML provides the clinical internship portion, and the Medical College of Georgia provides online courses.

OML uses a Web-connectivity system from 4Medica for result reporting and order entry. Whitehead says physician clients have been very willing to input their test orders as long as the system was interfaced to their office practice management system.

In the future, Whitehead believes primary care and internal medicine physicians will be looking for labs to provide more and more consultative support.



John Newby, MD

John Newby, M.D., medical director at **Hagerstown Medical Labs** (HML-Hagerstown, MD), says HML is trying to partner with other labs in adjacent markets so that it's in a better position to

negotiate managed care contracts. "Managed care and third-party payers have been unwilling to carve out lab contracts, even though our service is better than the na-

tional labs," he notes. "We have five pathologists at our lab, and physicians can call us directly at any time. It's very hard to get physician-to-physician contact at the big labs," he adds.

HML is an independent for-profit lab owned by Washington County Health System. HML operates labs at Washington County Hospital and Robinwood Medical Center as well as eight PSCs in northern Maryland. HML has 180 employees and about \$16.5 million in annual revenue.

Newby has kept a close watch on the lab accreditation controversy that has resulted from quality problems discovered by state health inspectors at Maryland General Hospital [see *LIR*, October 2004, pp. 1, 5-9]. He notes that Maryland's House and Senate are each working on new legislation aimed at improving the lab inspection process. One of the biggest changes he sees coming is stricter interpretation of CLIA rules by CMS and state health department regulators.

In particular, Newby says that labs will now be held accountable for the quality of specimens they receive. For example, if a physician office sends in a specimen that has been mislabeled, it will be the lab's job to contact the physician office and get the problem corrected. "We never thought we'd be held accountable for things we have no control over. This will have major consequences for all labs," adds Newby.



Lynel Vallier

Lynel Vallier, administrative laboratory director at **Boulder Community Hospital** (BCH-Boulder, CO), says the outreach program at BCH grew by about 14% in 2004 to reach 650,000 billable tests; inpatient volume was up 6% to 550,000 billable tests. BCH, which has 135 lab employees/92

FTEs, is a 265-bed acute-care hospital that serves the north Denver area.

Vallier attributes the outreach growth to BCH's willingness to go the extra mile for its physician clients. For example, he says that if a physician questions a test result because it does not fit the patient's medical profile, BCH will often send a split sample to another laboratory for confirmation.

Vallier says BCH has gained access to half a dozen managed care contracts through its participation in Frontline Laboratory Network (see *LIR*, August 2003, page 1). However, he says BCH still remains an out-of-network provider for several important contracts, including Aetna and Cigna. He notes that the two big commercial labs have stepped up efforts to place more phlebotomists in physician offices.

Another challenge is floor space. Since the BCH lab was built in 1987, volumes have increased by five-fold, and the number of analyzers used is up three-fold. Therefore, Vallier says consolidation of platforms and high throughput is essential. He says BCH has begun evaluating the potential to put in place total lab automation (possibly in 2006).

BCH recently added a Web-based order entry system from CareEvolve.

In terms of menu expansion, Vallier says BCH is planning to add allergy testing, quantitative HIV and HCV, and DNA-based HPV testing in 2005.

"If you want to get into outreach, you have to invest in it," says Vallier. In particular, he emphasizes the need for sophisticated billing systems. BCH uses the billing management firm Quadax (Cleveland) for its managed care contracts and the hospital's billing department for other outreach clients. 🏠



ACLA Challenges Florida Medicaid Lab Contracting Terms

Florida's Agency for Health Care Administration (FAHCA-Tallahassee) has issued a new solicitation for a winner-take-all, three-year contract to provide independent laboratory services to Florida's Medicaid population. The goal is to trim Florida Medicaid's \$35 million in annual spending on independent lab services by between 10% and 50% using a combination of capitation, discounted fee-for-service, and a \$1 lab co-pay, according to the FAHCA's 150-page "invitation to negotiate."

Those independent labs who wish to compete must notify FAHCA in writing by Jan. 10, and provide their proposals by Feb. 7. AHCA aims to choose a winner by March 18 and award the contract by April 4. If there is no contract by April 1, the state must cut reimbursement for lab services by 10% below the current Medicaid fee schedule, as per the state legislature (HB 1835).

Alan Mertz, president of the American Clinical Laboratory Association (ACLA-Washington, DC), says that ACLA has already filed plans to challenge the proposed contract structure with FAHCA and asked for a hearing before a state administrative judge. ACLA contends that the contract, if awarded, will damage the quality and access of care for beneficiaries. Mertz also says the contract requires the winner to put in place a costly new information system to monitor lab utilization of all beneficiaries, and this may conflict with both HIPAA and state confidentiality laws. In addition, *LIR* has learned that at least three other organizations have filed notices to challenge the contract's terms. So it looks like the contracting process will get gummed up in dispute and Florida labs will instead be faced with an across the board 10% cut in Medicaid fees this spring, *LIR* observes. 🏠

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- AmeriPath 800-330-6565
- ARUP 801-584-5157
- Boulder Community Hospital 303-440-2273
- Clinical Diagnostics Labs 404-728-9004
- Chromosomal Labs 877-434-0292
- CPL 512-339-1275
- Exact Sciences 508-683-1200
- Hagerstown Medical Lab 301-665-4900
- Oregon Medical Labs 800-826-3616
- Sunrise Medical Labs 800-782-0282
- The Lab at Steamboat 970-879-8468

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