



Your Independent Source for Business & Financial News

# LABORATORY

# INDUSTRY REPORT™

Vol. 14, Iss. 13, July 3, 2014

## HIGHLIGHTS

### TOP OF THE NEWS

- Quest invests in two logistics centers..... 1
- AACC pushes back on New York blood glucose regulation ..... 1
- Ameritox wins \$14.8 million verdict against Millennium Laboratories ..... 2
- Aurora makes two pathology acquisitions to help boost growth..... 3

### INSIDE THE LAB INDUSTRY

- Addressing the coming pathology shortage..... 4

### INDUSTRY BUZZ

- NeoGenomics revises guidance upward on strong sales ..... 8

[www.G2Intelligence.com](http://www.G2Intelligence.com)



## Upcoming G2 Events

**Lab Institute 2014  
Inflection Point For Labs**

**Oct. 15-17, 2014**

**Hyatt Regency  
Washington, D.C.**

[www.LabInstitute.com](http://www.LabInstitute.com)

**Getting a Piece of the Private  
Payer Market: Lab Contracting  
Trends, Pricing Realities, and  
Business Outlook**

**Half-Day Symposium**

**Oct. 17, 2014**

**1 p.m. - 5:30 p.m.**

**Hyatt Regency on Capitol Hill  
Washington, D.C.**

[www.LabInstitute.com/Symposium](http://www.LabInstitute.com/Symposium)

## Quest Invests in Two Logistics Centers

**Q**uest Diagnostics has invested millions of dollars in two new logistics centers in Kansas and Florida in order to take management of the nation’s largest laboratory to what officials described as the “next level.”

The centers, in Tampa, Fla., and Lenexa, Kan., will build on existing Quest operations in both cities. Quest has a particularly strong presence in Florida, with clinical labs in Tampa, Miramar, and Orlando, as well as several dermatological pathology-focused labs and offices.

The 48,000-square-foot Tampa center, which will lead to the hiring of 350 new employees over the next year, includes a monitoring hub that will track both air and ground operations for Quest across the United States. The hub features a 250-square-foot display for viewing the transit of patient specimens in near real time from one of

*Continued on page 2*

## AACC Pushes Back on New York Blood Glucose Regulation

**T**he American Association for Clinical Chemistry (AACC) has raised concerns about New York regulators jumping the gun on draft federal regulations regarding the use of blood glucose meters in hospitals.

A new directive by the New York State Department of Health requires that any provider using glucose meters for off-label purposes hold a state clinical laboratory permit for clinical chemistry and that only personnel licensed by the state Education Department are eligible to perform such testing. The state has determined that off-label use of a glucose meter is the equivalent of a high-complexity laboratory test and should be regulated accordingly.

Off-label uses include the monitoring of patients in hospitals—whose blood glucose fluctuations may foretell some pending complications—as well as for screening for diabetes at health fairs and other community events.

Although the AACC does not object to regulation of off-label uses of

*Continued on page 7*

### ■ QUEST INVESTS IN TWO LOGISTICS CENTERS, *from page 1*

Quest's 2,200 patient service centers and other patient locations in the United States. It also will be able to monitor the company's fleet of 3,000 vehicles and 20 aircraft.

"In the past, these functions were spread out in different areas of the U.S. By concentrating these capabilities in two state-of-the-art centers, we can standardize services and introduce new ones like best-in-class quality management and Web-based dispatch," said Quest spokesperson Wendy Bost.

The need for improved logistics has been growing in the laboratory business in recent years, as many labs are competing on speedier turnaround times and the quality of their courier services. Many labs have been using GPS tracking and other methods to keep closer tabs on drivers and to ensure specimens arrive for testing intact.

Quest is spending \$9.3 million on the Tampa facility, which will also contain much of the company's human resources division, Bost said.

The company's outlay for the 78,000-square-foot Lenexa facility, which is in a leased building, was unavailable. Some 550 new employees will be hired in Kansas.

The Florida facility is being touted for political points. "Quest Diagnostics' investment in the Tampa Bay region is great news for Florida families. These 350 new jobs will mean more Floridians will be able to provide for their family and live the American Dream," said Florida Gov. Rick Scott.

"This new facility will enhance our economic vitality and professional career opportunities, and strengthen our reputation as a center of commerce and innovation in health care," said Tampa Mayor Bob Buckhorn.

*Takeaway: Quest Diagnostics is making a significant investment in improving the overall logistics of its operations.* 

## Ameritox Wins \$14.8 million Verdict Against Millennium Laboratories

**T**he litigation between Ameritox and Millennium Laboratories has come to an end—for now—with Ameritox coming out on top.

A federal jury in Florida awarded Ameritox \$14.8 million to compensate it for claims that Millennium had engaged in unfair competition due to its distribution of hundreds of thousands of free point-of-care urine testing cups that included testing strips and had a retail value of about \$5 apiece. The award included \$12 million in punitive damages.

The Baltimore-based Ameritox sued the San Diego-based Millennium in 2011, claiming that the distribution of the testing cups amounted to kickbacks and illegally cut into its business. Millennium countersued, but the jury rejected its claims.

"All Ameritox wanted was a level playing field, and we're pleased that the jury rejected Millennium's practice of providing free point-of-care test cups to physi-

cians,” said Scott Walton, Ameritox’s chief executive officer. “The ruling underscores our belief that the significant health care challenges facing our country require steadfast adherence to the highest compliance standards, ethical business practices, and quality of service.”

In a statement, Millennium said it vehemently disagreed with the verdict and that it was compliant with all statutes regarding kickbacks.

“Although the jury’s decision impacts Millennium’s cup program in only four states, affecting only a small percentage of our customers, we have voluntarily agreed to suspend the program nationwide and will take immediate action to ensure full compliance while we appeal the decision,” the company said. “The jury’s decision does not affect the vast majority of Millennium customers, who either purchase cups and seek reimbursement for that testing or choose not to perform point of care testing at all.”

*Takeaway: The use of seemingly innocuous medical devices for marketing can wind up costing a laboratory millions of dollars in the long run.* 

## Aurora Makes Two Pathology Acquisitions to Help Boost Growth

**A**urora Diagnostics has been on the acquisition trail, buying up two dermatopathology practices in the past month.

In early June, it acquired Mid-Atlantic Pathology Services, a four-physician practice based in Sterling, Va. Toward the end of the month, it acquired Hallmark Pathology PC, based in Medford, Mass.

The terms of the transactions were not disclosed. Both are in states where Aurora does not have any practices. The Florida-based Aurora currently does business in 11 states.

Officials with the company were not immediately available to provide any details about the transactions.

In a statement, Aurora Chief Executive Officer Daniel Crowley suggested that more deals may be announced soon. “Our strategy is to pursue synergistic and accretive transactions, and we believe there is a robust pipeline of such opportunities,” he said.

Aurora may be using its purchasing power to boost its sagging revenue. According to its most recent filings with the Securities and Exchange Commission (SEC), it reported a loss of \$6.6 million on revenue of \$57 million. For the first quarter of 2013, it reported a loss of \$7.7 million on revenue of \$61 million.

In its SEC filing, Aurora said payment reductions from the Medicare program and increases in expenses have crimped its cash flow. It said it would make acquisitions “which it believes would add to earnings and performance” and help it meet the mandated ratios in order to access its credit facility.

*Takeaway: Aurora Diagnostics may be using acquisitions to add to its bottom line as opposed to organic growth.* 

# Inside The Lab Industry



## Addressing the Coming Pathology Shortage

The United States has been facing a shortage of physicians for at least a decade now, and it is expected to grow more acute in the coming years.

However, the shortage of pathologists is expected to grow quite dire over the next 15 years, with the downward slide beginning as early as next year. It could even place pressure on the growing business of molecular assays and personalized medicine.

That is the opinion of Health Care Development Specialists Inc. (HCDS), the Florida-based lab and pathology consulting firm. It recently issued a special report to its clients on the shortage, which is available for download at [www.hcdsinc.com](http://www.hcdsinc.com). That report itself is based in part on a study published late last year in the *Archives of Pathology & Laboratory Medicine*.

That study, which was co-authored by a group of leading pathologists, concluded that the ranks of the nation's pathologists would be thinned by a large number of retirements starting next year and continuing until 2030.

### Dramatic Drop Around the Corner

By 2030, the rate of practicing pathologists is expected to decline from 18,000 to 14,000, or 3.7 per 100,000 of population. That would be a 32 percent decline from the current rate of 5.7 per 100,000.

"We observed that because pathologists play a pivotal role in diagnosing disease, projected shortages pose serious implications for patient care," HCDS said in an introductory note to the client alert.

The situation was serious enough for the College of American Pathologists (CAP) to hold a special summit late last year to discuss the issue.

The reasons for the decline are numerous, but it is pegged primarily to the fact that the active chronological age of pathologists is among the oldest of the medical specialties—75 percent are 45 years or older, 41 percent are older than the age of 55, and 12 percent are older than 65. By contrast, only 26 percent of the nation's pathologists are under the age of 44. And the current average age is around 57, which while not old is not exactly youthful.

Moreover, the number of residency programs has shrunk dramatically over the past 50 years, from about 700 in the early 1960s to less than 150 today. CAP President Gene Herbek, M.D., estimates that those programs—which produce about 500 new pathologists per year—is about 150 to 200 short annually of preserving the current workforce levels.

Given that few new medical schools have opened in the past decade despite the general overall shortage of physicians, and policymakers are incentivizing the creation of more residency slots for primary care physicians rather than specialists, industry observers do not think the pipeline of newly minted pathologists is expected to expand any time soon.

### **Already Overextended**

What does such a projected drop in the population of practicing pathologists portend?

Barry Portugal, the president of HCDS, believes it could become worse for health care delivery sooner rather than later. He noted that pathologists—particularly those practicing in the hospital setting—are already overextended due to the extra duties they are asked to perform, such as managing utilization and blood supplies, acting as laboratory directors, and other side work. They also perform additional services such as special consultations and special stains.

“There’s not even a reference to an additional workload in many studies, and I think because of that the timetable [for the shortage] will be sooner rather than later,” Portugal said.

That is definitely the case for Herbek. In addition to his pathology practice, he oversees blood management at Methodist Hospital in Omaha, Neb. He also serves as the laboratory director at Methodist Women’s Hospital and devotes time to developing care guidelines and analyzing test algorithms for clinical appropriateness as part of Methodist’s accountable care initiative.

“Those are the kinds of things we’re doing on a more regular basis,” Herbek said, estimating the extra workload to be about 10 hours per week, or about 20 percent above his current workload as a pathologist. Of course, that is completely separate from the work he does on behalf of CAP.

### **Extending Extenders**

But not all of the scenarios are dark. There is the possibility of adding to the “pre-signouts” job duties to allied staff such as cytopathologists, histotechnologists, pathology assistants (PAs), and doctorate-level clinical scientists. In a report on last year’s workforce summit, CAP recommended using cytopathologists to conduct testing for the human papillomavirus, much in the way they currently conduct much of the work connected to Pap smears.

“With their background in biology and genetics, prerequisites for laboratory training programs, cytotechnologists possess the knowledge base required for molecular testing,” the report said. “In response to changes in practice increasing demand for cervical cancer screening utilizing molecular techniques, broader training offered in cytotechnology education programs will provide graduates the relevant broad skills to continue as key health care professionals in women’s health.”

*“There’s not even a reference to an additional workload in many studies, and I think because of that the timetable [for the shortage] will be sooner rather than later.”*

*– Barry Portugal, President,  
Health Care Development Services Inc.*

## INSIDE THE LAB INDUSTRY

Herbek noted that pathologists will have to allocate more duties to extenders in the future.

“We will need to rely on them to help us get the job done, particularly in getting the diagnoses and lab testing out in an efficient manner,” he said. Friction regarding scope-of-practice issues is not likely to surface as in primary care or other specialties because the relationships with pathologists and their extenders tends to be collegial, according to Herbek.

The HCDS report also recommended the use of extenders to help close gaps in the coming pathologist shortage. It suggested using pathology assistants for a variety of duties, including coding, tissue procurement for research purposes, training of histotechnologists, and other aspects of personnel management.

But the report also noted that while using extenders is crucial, so is recruiting them. Portugal observed that PAs and other extenders are in short supply themselves.

And while hospital-based pathology practices may have the resources to hire extra personnel to assist the doctors, that is not necessarily the case for independent practices, most of which have 10 doctors or fewer. A PA can command a salary of \$90,000 to \$140,000 a year; a cytotechnologist, up to \$75,000; and a histotechnologist, up to \$50,000.

***“We will need to rely on [extenders] to help us get the job done, particularly in getting the diagnoses and lab testing out in an efficient manner.”***

***– Gene Herbek, M.D., President,  
College of American Pathologists***

Given the current financial environment for pathologists, who have been hit hard by ongoing reimbursement cuts, many may be reluctant to hire additional staff.

“In academic settings or in large pathology groups, the use of a PA is something that is widespread. But when you have a preponderance of pathology groups with 10 doctors or less, they may decide not

to use PAs because the money may have to come out of their own pocket,” Portugal said. “If you’re already facing substantial reductions in your income, some of them may simply try to work longer hours rather than invest in extenders.”

Many pathologists may not have a choice. Herbek noted that the specialty does not require the physical skills—or the physical stresses—of other specialists, such as surgeons. As a result, many could choose to delay their retirements.

Currently, CAP’s workforce staff pegs the average retirement age for a pathologist at 71—a half-dozen years beyond qualifying for Social Security and in line with a U.S. labor force that is working years beyond what they had in the past.

“And that [retirement age] is pretty conservative,” Herbek said.

***Takeaway: The pathology community and its advocates will have to find creative ways to stretch the dwindling numbers of newly minted pathologists.*** 

### ■ AACC PUSHES BACK ON NEW YORK BLOOD GLUCOSE REGULATION, *from page 1*

the meters, it is concerned that New York installed its own guidelines while the FDA is still hammering out a final version of its own rules.

“AACC recognizes that there are many complicated and difficult decisions that must be made related to the use of blood glucose meters in off-label situations, such as who can perform the tests, the settings in which these tests can be performed, and what types of studies are required,” said AACC Chief Executive Officer Janet B. Kreizman. “We recommend New York wait and consider the efforts to review this issue by [the Food and Drug Administration (FDA)], as well as the Centers for Medicare and Medicaid Services, before making and implementing policy changes that will significantly impact hospitals within their state and possibly nationwide.”

Although New York state decisions regarding laboratory regulations are not binding on other states, organizations with CLIA deeming authority often do look at regulatory moves that are made in the state as potential guidelines as part of their own decisionmaking process.

For better or for worse, glucose meters have become a staple of both consumer and clinical health care as diabetes has become a nearly endemic condition in the United States. The devices, which often cost as little as \$10, are used by millions of Americans every day to monitor their blood sugar. A variety of studies have shown that monitoring of blood glucose in the hospital setting—whether the patient is diabetic or not—can provide an additional vital sign that can help reduce complications and often shorten average lengths of stay.

However, there have been concerns about the use of the meters in the hospital setting, particularly regarding the potential spread of hospital-acquired infections when the devices are not properly cleaned between uses, and the accuracy of the readings they provide when used during the care of critically ill patients.

In January, the FDA issued draft guidelines regarding how such devices should be designed and used in the hospital setting. Although the FDA has yet to issue final guidelines, the New York state directive is being implemented as if the guidance is final, according to James Nichols, a professor of pathology at Vanderbilt University and chair of the AACC’s governmental relations committee.

As a result of the change, Nichols noted that many hospitals in New York would be forced to utilize far more costly blood gas or alternative analyzers. There might be 10 blood gas analyzers in a hospital at any given time, versus 100 or more blood glucose meters, necessarily limiting availability of testing if glucose meters can no longer be utilized for intensive insulin management.

The New York regulation also prohibits staff that had been routinely monitoring blood glucose levels from doing so—such as registered and licensed vocational nurses.

“It’s going to be a major impact,” Nichols said.

Although the AACC has asked New York to relent on its decision until the FDA makes its final determination, there has been no word yet on whether it might relent.

*Takeaway: Even a fairly routine monitoring test can have implications for laboratory managers.* 

## NeoGenomics Revises Guidance Upward On Strong Sales

**N**eoGenomics Laboratories has entered a growth spurt. The Florida-based laboratory revised its guidance upward for the second quarter, nearly a month before it is scheduled to release its earnings report on July 17.

The company now forecasts that its revenues for the second quarter will be between \$20 million and \$20.5 million. That's up about 7 percent from its previous guidance of between \$18.8 million and \$19.3 million.

"We experienced exceptionally strong year-over-year volume growth in April and May driven by a continued increase in the number of new customer accounts," said NeoGenomics Chief Executive Officer Douglas Van Oort. "The growth is geographically broad-based and is being fueled by the increased size and productivity of our sales team and by new product activity."

A year ago, NeoGenomics reported second-quarter net income of \$273,000 on revenue of \$15.6 million. Its revenue was down slightly compared to the second quarter of 2012. Despite the revenue growth, NeoGenomics did not raise its estimates on net income, keeping it at between nothing and 1 cent per share, essentially unchanged from the year-ago quarter. That is presumably the result of increased general and administrative expenses to help generate the additional revenue, according to analysts Amanda Murphy and J.P. McKim of William Blair & Co.

William Blair raised its end-of-year revenue estimates for NeoGenomics to \$77.4 million. In 2013, the company reported revenue of \$66.5 million.

Late last year, NeoGenomics entered into an agreement with pharmaceutical giant Covance to provide anatomic pathology and specialty laboratory testing for clinical trials. Under the terms of the agreement, NeoGenomics will provide the professional interpretation for all of Covance's testing globally and the technical component of tests being performed outside of the United States. Although Murphy and McKim think the alliance will be greatly beneficial to NeoGenomics in the short term, they do not believe that it helped bump up sales in such a short period of time.

*Takeaway: NeoGenomics is in a period where revenue is expected to grow dramatically, although whether it becomes a solidly profitable company remains to be seen.* 

### References

|   |   |   |
|---|---|---|
| American Association for Clinical Chemistry<br>800-892-1400 | College of American Pathologists<br>847-832-7000      | NeoGenomics Laboratories<br>239-768-0600            |
| Ameritox<br>877-596-2224                                    | Health Care Development Services Inc.<br>847-498-1122 | New York State Department of Health<br>866-881-2809 |
| Aurora Diagnostics<br>866-420-5512                          | Millennium Laboratories<br>858-451-3535               | Quest Diagnostics<br>800-222-0446                   |

**Note our change of address and phone numbers effective immediately.**

**To subscribe or renew LIR, call now +1-603-357-8101, 800-531-1026**  
(AAB and NILA members qualify for a special discount, Offer code: LIRN11)

**Online:** [www.G2Intelligence.com/LIR](http://www.G2Intelligence.com/LIR)

**Email:** [customerservice@G2Intelligence.com](mailto:customerservice@G2Intelligence.com)

**Mail to:** G2 Intelligence  
24 Railroad Street  
Keene, NH 03431-3744 USA

**Fax:** +1-603-357-8111

*Multi-User/Multi-Location Pricing?*  
*Please email [jping@G2Intelligence.com](mailto:jping@G2Intelligence.com) or call 603-357-8160.*