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# LABORATORY

# INDUSTRY REPORT<sup>®</sup>



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Vol. 13, Iss. 3, February 1, 2013

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## PathCentral Launches Cloud-Based Network To Link Chinese Hospitals, American Pathologists

**P**athCentral has introduced an online network that will link thousands of hospitals in China with pathologists in the United States.

The network is the result of a joint venture between PathCentral, which is based in Irvine, Calif., and the Chinese firm Kindstar Globalgene Technology. It will allow pathologists practicing in the United States to deliver results to Chinese physicians via cloud computing.

Kindstar, based in Wuhan, has labs in that city, as well as Beijing and Shanghai. It provides diagnostic testing to more than 3,300 Chinese hospitals. Although it was founded only a decade ago, it is the largest such testing business in China.

"Demand for pathology consultants in China is growing at a rate that simply cannot be accommodated locally," said Shiang Huang, M.D., Kindstar's chief executive officer. The dramatic growth of the Chinese economy, plus the country's recent investment of hundreds

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## Quest's 2012 Performance Flat; Changes Not Expected Until Mid-2013

**P**lateau. It's a geographic item usually associated with the American Southwest, but it can now also be attributed to New Jersey—more specifically, the financial landscape for Madison-based Quest Diagnostics.

Quest's revenue for 2012: \$7.38 billion. Its revenue for 2011: \$7.39 billion.

The nation's largest laboratory did show significantly better results in terms of net income, which grew 18.2 percent in 2012 versus 2011, from \$470.6 million to \$555.7 million. That was despite the fact that damage and disruption from Superstorm Sandy was blamed for an estimated revenue hit of \$21 million and operating earnings of \$21 million during the fourth quarter that ended Dec. 31. Positive cash flow was also up for the year, to \$1.2 billion in 2012 compared to \$987 million in 2011.

However, much of that improved performance is linked to the \$241 million settlement Quest paid in May 2011 to settle Medicaid over-billing charges in California—an expense that was off the books in 2012.

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### ■ **PATHCENTRAL LAUNCHES CLOUD-BASED NETWORK**, *from page 1*

of billions of dollars in health care infrastructure, has driven a surging demand for pathology services in recent years.

Chinese pathologists already have a fairly close professional relationship with their colleagues in North America. Its advocacy group, the International Association of Chinese Pathologists, typically has its annual meeting in conjunction with the United States and Canadian Academy of Pathology.

According to Huang, the arrangement will allow Kindstar's hospital clients to have their pathology specimens examined by U.S. physicians, whose diagnostic skills are considered to be more sophisticated than physicians' in China. "This is a tremendous milestone for the medical community in China and for our ability to serve patients throughout the country," he said.

Kindstar has been using PathCentral's anatomic pathology laboratory information system, or APLIS, since 2011, to link the hospitals it serves in China electronically.

PathCentral CEO Jaye Connolly said the new network represents the next step in the company's plan to link pathologists electronically throughout the world. 

## **Boston Children's, Life Technologies Form Genetic Testing Venture**

**I**n a second major foray into genomics by a major New England provider in recent weeks, Boston Children's Hospital has formed a company to develop new molecular tests and related products.

Children's has entered into a deal with Carlsbad, Calif.-based Life Technologies Corp. to form Claritas Genomics. The deal, which was announced at last month's J.P. Morgan Healthcare Conference in San Francisco, comes on the heels of an announcement by Boston-based hospital operator Partners Healthcare that it planned to offer whole-genomic sequencing and testing to its patients.

Exact terms of the transaction were not disclosed, but Children's will be a majority owner of the new entity, with most of the testing taking place on its campus. The hospital will integrate its existing genetic diagnostic lab into Claritas. That lab currently performs more than 100 types of genetic tests.

"Boston Children's has already invested significantly to accelerate genomic discovery for patients with rare diseases, cancer, and autism and to profile individual responses to medications. We now have a practical paradigm for taking genetic and genomic research discoveries to the bedside, and we're excited to be able to scale up and offer this capability to patients everywhere," said David Margulies, M.D., executive director of the Gene Partnership at Boston Children's Hospital. "Through a set of network collaborations and via electronic communications, we plan to provide interpretive services around the world."

In addition to the partnership with Life Technologies, Boston Children's plans to develop relationships with other children's hospitals in the United States and in other nations in order to share data.

Claritas will also work to validate what officials say is the “clinical utility” of the Ion Proton Sequencer, a genome sequencer Life Technologies introduced last year that is about the size of a toaster oven and can sequence an entire human genome in one day for about \$1,000. Although it has had sales to several large universities and to researchers in Australia and Korea, it is still not being widely utilized at hospitals in the United States. The instrument will be used to develop new tests by Claritas’s researchers.

“While a number of academic and private ventures are offering genomic sequencing and molecular diagnostics to the public, no other partnership has integrated all the elements—fast, accurate genomic sequencing, bioinformatics, CLIA expertise, and access to researchers and clinicians who can interpret the data in a meaningful way,” said Sandra Fenwick, Boston Children’s president and chief operating officer. 

### PerkinElmer, Verinata Collaborate on Prenatal Test

**P**erkinElmer and Verinata Health have entered a collaboration agreement to distribute the latter’s fetal chromosomal abnormality test.

The agreement was announced just a couple of days after San Diego-based genome sequence instrument manufacturer Illumina entered into terms to acquire Verinata for \$450 million.

Based in Redwood City, Calif., Verinata introduced its chromosome test, known as verifi, last February.

It uses Illumina instruments to analyze blood samples for signs of Down syndrome, Patau Syndrome, and Edwards Syndrome in fetuses who may be considered high-risk (e.g., the mother is over 35 years of age, has a prior family history of chromosomal abnormalities, or there are abnormalities on an ultrasound test).

Results can be obtained as early as 10 weeks into gestation. The test retails for about \$1,200, according to published reports.

Prenatal testing has decreased the number of abnormal births in the U.S. by a significant amount in recent years, according to research.

Under the terms with PerkinElmer, the Waltham, Mass.-based testing giant will be the exclusive partner with Verinata to market and distribute the verifi test. Verinata will continue to perform the test at its lab in Redwood City.

“Integrating Verinata’s noninvasive prenatal test with PerkinElmer’s existing solutions ensures that physicians and patients have early access to the most advanced testing solutions to help protect the health of mothers and babies and we look forward to working with Illumina,” said Robert Friel, PerkinElmer’s chief executive officer.

“Collaborating with PerkinElmer provides a great opportunity to . . . offer expectant mothers greater access to complete high-quality screening and diagnostic tests,” said Jeff Bird, M.D., Verinata Health’s chief executive officer. 

# Inside The Lab Industry



## Labs Plugging Into Health Information Exchanges; Solstas, Quest, LabCorp All in Deals

Rochester, N.Y., has seen better days as a commercial hub. The upstate city near the Canadian border has lost most of its big employers over the decades, and its flagship company, Eastman Kodak, filed for bankruptcy last year.

But just as the photography giant simplified and streamlined the sales of film and cameras 125 years ago, another enterprise in Rochester may be doing the same to the ordering and delivery of laboratory tests.

The Rochester Regional Health Information Organization (RHIO) is one of scores of provider consortiums that have sprung up in the last decade to simplify the sharing of digitized patient medical records over broad geographical regions. In 2008, it launched the record-sharing service among providers in a 13-county area. The following year, it created a digital delivery service for laboratory results.

***“Lab is a no-brainer for this.”***  
—Jessica Hasler,  
Rochester RHIO

Although Rochester has only 210,000 residents and the surrounding metropolitan area barely tops 1 million, its RHIO is delivering nearly 500,000 lab test results a month to about 1,000 providers. It plans to launch an ordering service later this year, initially in conjunction with the region’s biggest laboratory, ACM.

“Lab is a no-brainer for this,” said Jessica Hasler, the Rochester RHIO’s director of community services. “It [contains] such a high volume of results, and is such a critical portion of the physician workflow.”

RHIOs, which also go by the acronym for health information exchanges, or HIEs, have been particularly productive in the past few years. Their growth has been spurred in part by the Health Information Technology for Economic and Clinical Health Act (HITECH), a health care-related part of the economic stimulus legislation signed into law in 2009 that has dangled tens of thousands of dollars in incentive payments to individual physicians to install electronic medical record (EMR) systems. And as the RHIOs/HIEs continue their development, they could wind up remaking the decades-old mashup of faxes, courier deliveries, and reams of easily misplaced paper that still comprise a large part of the laboratory industry’s ordering and delivery infrastructure.

“What we do is provide the final mile,” said Dan Porreca, executive director of HealthELink, an HIE/RHIO that serves Buffalo, N.Y., and handles the patient records for about 1.5 million individuals. HealthELink’s delivery service populates electronic medical records with lab results directly. Porreca estimated that HealthELink handles about 95 percent of the lab records produced in the region.

## INSIDE THE LAB INDUSTRY

Although Michigan Health Connect in the Detroit area has just started up its lab record delivery service, its executive director, Dan Dietzman, sees it as a potential timesaver not only for providers but also as a tool to help improve patient outcomes as well.

“Folks often stick a [lab order] in their purse or their car, and don’t go for a couple of weeks,” for draws, he noted. Having everything on a fully electronic system provides better tracking—and quicker compliance.

Moreover, the exchanges also have the capability of coding many of the results in LOINC, a database for lab names and codes, whether the specific providers use that coding or not. That allows for better tracking of statistical and demographic data for both the labs and providers, Porreca said.

Although many RHIOs/HIEs are undertaking the painstaking work of marrying the myriad of EMR systems into a single accessible portal for providers—Michigan Health Connect has done so with 40 different applications, Rochester with 19, and HealthELink with 10—most of these organizations are nonprofits and subsist primarily on state and federal grants and the relatively modest participation fees they charge

*“Solstas has been an excellent partner from the start—they just jumped right in.”*  
—Whitney Baker,  
North Carolina Health  
Information Exchange

providers. As a result, they are catching the attention of laboratories whose management may be seeking alternatives to investing millions of their own dollars into IT infrastructure to better serve their customers.

### **Big Labs and HIEs**

Officials with three large national laboratories—Quest Diagnostics, LabCorp, and Solstas Lab Partners—were not particularly forthcoming about their plans for HIEs/RHIOs. However, several officials with those networking organizations confirmed they have either inked contracts or are in discussions to participate in their infrastructure.

One such RHIO/HIE covers the entire Tar Heel State. The North Carolina Health Information Exchange is launching its record-sharing system within the next few weeks, and it will do so with data-sharing agreements in place with Solstas and LabCorp, both of which are headquartered in North Carolina. LabCorp Chief Executive Officer David King sits on the North Carolina HIE’s board of directors.

“Solstas has been an excellent partner from the start—they just jumped right in,” said Whitney Baker, the North Carolina HIE’s manager of marketing and customer advocacy.

Solstas reached a participation agreement with the North Carolina HIE last May, according to Baker. Although Solstas declined comment for this article, in a press release it issued at the time of the agreement, its chief information officer, Bryan Firestone, noted that “accessible health information is at the center of the next wave in patient care. This collaboration with the North Carolina HIE is in direct correlation with that initiative, as well as Solstas’s core values of enhancing patient care.”

As part of the agreement, Solstas and LabCorp will post “courtesy copies” of laboratory reports as part of the patient records that will be shared between the providers in the consortium.

They will show up whenever a provider calls up a patient record.

In addition to those two national labs, the North Carolina HIE is currently in negotiations for a similar agreement with Quest Diagnostics, according to Baker.

In an e-mail response, Quest spokesperson Wendy Bost termed such negotiations “rumors.” However, Bost added that “we are in discussions with providers regarding potential participation in several exchanges. Quest Diagnostics has many capabilities, such as electronic connectivity and strong physician and hospital relationships, which closely align with the requirements of an effective health exchange.”

Such attributes are prized by Dietzman. He added that his HIE/RHIO is in talks with both Quest and LabCorp, although no definitive agreements have been reached.

“I kind of want the Quest deal. Everything with a hospital relationship is built from scratch. With a national lab, it would be like flipping a switch,” he said—primarily because they are already well-prepared to interface with a variety of EMR systems.

Currently, Michigan Health Connect is in the first stages of delivering lab records—it is only moving about 6,000 per month, primarily through the laboratory at Saint John Hospital Medical Center in Detroit.

But Dietzman expects deliveries to grow quickly, particularly as more of the 47 hospitals participating in the exchange join the service.

However, he sees one significant challenge with the hospital labs themselves: Changing their operations and cultures.

“The biggest challenge in the ordering is not the technology, it is how the lab operates,” he said. “If you’re used to paper in the bag, and now you say, ‘we have to start using electronic messages, coding messages, and insurance tables,’ how do you efficiently accommodate the operations? The technology makes it easier, but making the adjustment is a little bit more of a steeper curve.” 

### ■ QUEST'S 2012 PERFORMANCE FLAT, *from page 1*

For the fourth quarter, net income was \$55.8 million on revenue of \$1.77 billion, down from \$189.5 million on revenue of \$1.84 billion during the fourth quarter of 2011.

Quest officials did not promise much immediate improvement. Officials said the company's 2013 guidance projected revenues would remain flat, as would operating income. However, earnings per share are expected to grow from the \$3.46 posted in 2012 to between \$4.35 and \$4.55 per share in 2013. That's linked primarily to a combination of stock buybacks and expense reductions.

"In 2013 our focus will continue to be driving operational excellence and restoring growth," said Chief Executive Officer Steve Rusckowski. He added that the restructuring plans he's undertaken since being appointed CEO in the middle of last year will begin to show results after the second half of the year.

Among Rusckowski's changes has been a refocusing of the company on two core assets: traditional diagnostics and diagnostic information services. That has included a restructuring that is in the midst of cutting 600 management-level positions. It is expected to save the company as much as \$500 million a year moving forward. 

## ARUP, Oncimmune Collaborate on Test For Early Detection of Lung Cancer

**S**alt Lake City-based ARUP Laboratories has teamed with Oncimmune USA to offer a new blood-based test that can provide early detection of lung cancer.

As part of the arrangement between the two companies, ARUP will send all samples for Oncimmune's laboratory in Kansas City, Kan., to run the assay, known as the EarlyCDT-Lung test. It measures autoantibodies in blood that form in response to the early stages of carcinogenesis.

"We believe that our partnership with ARUP can improve the well-being of many individuals who are at risk for developing lung cancer," said Greg Stanley, Oncimmune's chief commercial officer. Although the company is based in the United Kingdom, it has extensive operations in the United States.

According to peer-reviewed clinical data, the Oncimmune test has one-seventh the rate of false positives that occur with computerized tomography scanning. It currently is being used by about 2,000 physicians in the United States and is undergoing a randomized clinical trial in Scotland for high-risk patients.

"We are delighted to make the EarlyCDT-Lung test available to our clients through this partnership with Oncimmune," said David Grenache, M.D., ARUP's medical director of special chemistry. "This test represents a novel . . . approach to testing those individuals at high risk of developing lung cancer. We feel it is a welcome addition to our extensive oncology test menu and complements our existing lung cancer test offerings."

About 160,000 Americans die of lung cancer every year, and more than 226,000 new cases are diagnosed. Mortality rates tend to be lower if the disease is detected in its earlier stages. 



# INDUSTRY BUZZ

## Quest Puts HemoCue Up for Sale

In its continuing march toward a streamlined business model, Quest Diagnostics has put its HemoCue division on the sales block.

HemoCue, with operations based in Cypress, Calif., develops and manufactures handheld devices for determining hemoglobin, glucose, and white blood cell counts. Quest bought the firm for \$420 million, although some analysts say the final purchase price was closer to \$440 million. Quest has not disclosed any potential suitors for the company.

When Quest originally announced the acquisition exactly six years ago, HemoCue was intended to play an integral part of its Care360 electronic portal for physicians.

“Technology is enabling diagnostic testing to move closer to the patient, and the acquisition of HemoCue and its exciting product pipeline gives us a strong presence in this emerging market,” said former Quest Chief Executive Officer Surya N. Mohapatra, at the time the deal was announced. “This will help doctors improve the way they diagnose, monitor, and treat disease.”

Mohapatra left Quest last year. His successor, Steve Rusckowski, has made it clear the company required a major operational shakeup after a couple of years of flat revenue growth. Last fall, Quest announced a streamlining of layers of management, with a refocus on traditional diagnostics and diagnostic information services.

Quest’s announcement it would shed HemoCue came just a couple of weeks after its New Year’s Eve announcement it had sold its OralDNA division to Access Genetics for an undisclosed sum.

“The company’s plan to sell HemoCue comes as no surprise, given Quest’s indication that it was reviewing strategic options for HemoCue and Celera in an effort to refocus the business on traditional lab services,” said a recent report by Amanda Murphy and Sylvia Chao of investment banking firm William Blair & Co. in Chicago. They added that HemoCue’s sales—which were less than \$100 million a year when Quest acquired it—had likely not ramped up as projected.

“We expect more divestitures of nonstrategic product assets, although management has said it intends to keep Focus Diagnostics’ infectious disease testing [and point-of-care products] business,” Murphy and Chao said. 

### References

ARUP Laboratories 801-583-2787	Oncimmune 913-583-9030	Rochester RHIO 877-865-7446
Life Technologies 800-955-6288	PathCentral 949-468-3419	Solstas Lab Partners 336-664-6100
North Carolina HIE 919-926-1042	Quest Diagnostics 800-222-0446	Verinata Health 650-503-5200

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