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LABORATORY INDUSTRY REPORT®

Kimberly Scott, Managing Editor, kscott@G2Intelligence.com

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HIGHLIGHTS

Medication Testing Labs Create Formal Coalition to Set Industry Standards for the Sector

Four of the nation's biggest specialists in medication testing have formed a coalition to advance treatments and standards of care for patients who take pain medication.

The organization, known as the Coalition for Excellence in Medication Monitoring, was founded and is being funded by Baltimore-based Ameritox; Indianapolis-based AIT Laboratories; Woburn, Mass.-based Calloway Laboratories; and North Kingston, R.I.-based Dominion Diagnostics. Eric Rasmussen, the coalition's spokesperson, said other laboratories are also being invited to join. The organization has established a basic Web site, *medicationmonitoring.org*.

A Washington, D.C., law firm, Patton Boggs LLP, is currently managing the coalition's operations. No immediate plans are available for hiring separate staffing, said Rasmussen, who is a Patton Boggs associate attorney.

A joint statement issued by the labs said the coalition "will play a critical role in helping set standards for this evolving industry, so that clinicians and patients can be confident that they are receiving the most advanced and reliable monitoring practices available."

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Bio-Reference Earnings Barely Dinged by Sandy

Bio-Reference Laboratories (Elmwood Park, N.J.) wasn't spared from the wrath of Superstorm Sandy, but that did not deter the firm from posting its best earnings in history.

Although company officials estimate that Sandy cost Bio-Reference about $5 million in lost revenue, it nevertheless posted double-digit increases in overall sales and net income for the fiscal fourth quarter, ending Oct. 31.

Bio-Reference reported net income of $12.9 million on revenues of $176.1 million, increases of 22.9 percent and 16.4 percent, respectively. Year-ago net income was $10.5 million on revenues of $151.3 million.

"Despite the impact of the storm in the area, the company had no shut down whatsoever of laboratory operations," the company said

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Medication Monitoring Labs Establish Formal Coalition, *from page 1*

Although the testing of employees for drugs has decreased over the last decade, data suggest that market demand is growing for the testing of individuals for their use of pain medications, particularly powerful painkillers such as oxycodone. Such drugs are often abused or sold to third parties for as much as $30 per pill, industry observers said.

According to data from the Centers for Disease Control and Prevention (CDC), the number of Americans who have overdosed from prescription drugs has tripled since 1990, reaching more than 1,200 per month, while the number of hospital emergency room visits for issues related to pain medications have doubled since early this decade. Opioids were involved in more than 40 percent of drug poisoning deaths in 2008, the CDC recently reported. The abuse of prescription painkillers for nonmedical use costs insurance companies up to $72.5 billion each year, according to the CDC, providing a strong financial incentive for regular testing.

> ***"We want to get out in front and set a standard."***
> ***—Eric Rasmussen, Coalition for Excellence in Medication Monitoring***

As a result, medication labs are performing tests not only to determine levels of drug toxicity but also to confirm that pain medication patients are actually taking their medications in appropriate doses, said Phil Radford, chief executive officer of AvuTox, a testing firm in North Carolina.

In addition to testing for drug use or misuse, the medication monitoring labs also can play a role in preventing dangerous interactions if patients are prescribed multiple drugs to treat their medical conditions, officials said, which given the current state of prescription drug misuse, the labs believe is not the case.

Rasmussen said the coalition has come together for a variety of reasons but has been primarily spurred by limits the Centers for Medicare and Medicaid Services has put on drug testing in recent years for enrollees. Rasmussen noted that the limits on testing were based on perceptions by agency officials that such tests were being overutilized or improperly used.

"The coalition is trying to work with policymakers to communicate the clinical value of these tests, particularly in this time of an explosive growth of addiction," Rasmussen said.

Additionally, Rasmussen said that the coalition would create a code of conduct for testing laboratories.

"There has been some negative press about the industry in recent years, and a code of conduct is really a reaction to that," he said, "as well as establishing best practices of how laboratories should act in this space vis-a-vis to payers, physicians, and patients. We want to get out in front and set a standard."

Partners Healthcare Delving Into Personalized Molecular Medicine

Partners Healthcare, the Boston-based hospital system, will delve extensively into the personal medicine market beginning in early 2013.

Starting in January, Partners, which operates nine hospitals in Massachusetts, will offer whole-genome sequencing and interpretation to its patients in order for its medical staff to craft more effective treatment pathways. The testing will cost about $9,000, according to a report in the *Boston Globe*.

Partners has developed about 150 genetic tests on its own, primarily through its Partners Center for Personalized Genetic Medicine, a network of labs and technology development teams in Cambridge, Mass. It will combine those tests with a proprietary software system for analysis. The *Globe* report suggested that Partners will offer interpretation services to other providers and that Partners would use the service to distinguish itself from its competitors. Partners officials did not respond to repeated requests for comment.

"We expect the collaboration between our organizations to yield significant benefits to our patients, and to patients worldwide."
—Anne Klibanski, M.D., Partners Healthcare chief academic officer

The Partners system, which includes Brigham and Women's Hospital and Massachusetts Medical Center, has had a longtime dedication to personalized medicine. It initially founded its center for personalized genetic medicine in 2001 in conjunction with Harvard Medical School.

In September, Partners announced an alliance with San Diego-based Illumina Inc. to create support infrastructure for geneticists and pathologists, as well as networking tools to improve the interpretation and reporting process for genetic sequencing data. That would be accomplished by installing the Partners-designed software, known as GeneInsight, into Illumina's gene sequencing hardware. Initially, the alliance would work with a small group of reference and pathology labs on a pilot basis.

"We expect the collaboration between our organizations to yield significant benefits to our patients, and to patients worldwide," said Anne Klibanski, M.D., Partners' chief academic officer, in a prepared statement.

How a Lab Formulary Can Cut Hospital Costs

Choose wisely. That was the message of Paul C. Levy, M.D., a professor of medicine at the two-hospital University of Rochester Medical Center (URMC) system, regarding his experiences installing a laboratory formulary at his hospital. He discussed the experience at G2 Intelligence's Lab Institute, held in Arlington, Va., this past October.

Levy noted that test utilization greatly varies, by as much as 100 percent when individual medical practices are compared. As a result, costly tests such as computed tomography imaging to determine the nature of chest nodules are often unnecessary because so few are actual malignancies. In the lab realm, there is the potential overuse of prostate-specific antigen testing to find potential cases of prostate cancer. Both can lead to even more unnecessary and costly treatments, he noted.

> ***"What we tried to do is make sure someone who has been around the ball diamond longer signs off on the test."***
> ***—Paul C. Levy, M.D., University of Rochester Medical Center***

Rochester had a huge cost burden just from routine reference tests—more than $2 million a year in uncompensated testing before it launched its formulary program in 2009, according to Levy. Many of those tests were being ordered by nurse practitioners and physician assistants.

However, physicians were also ordering costly esoteric tests, including an $8,000 molecular array ordered for a single patient. And the results of many tests were coming in after patient discharge, greatly reducing their clinical value.

Under the formulary, an attending physician was assigned to approve such tests before they went to the lab.

"What we tried to do is make sure someone who has been around the ball diamond longer signs off on the test," Levy said, in order to avoid what he said were costly "fishing expeditions." And physicians were also required to attest that the tests they were ordering were medically necessary and would likely alter diagnoses and treatment plans while the patient was still admitted.

Rochester also studied the volume of its more common assays and brought some in-house, such as the vitamin D test. The results were dramatic: Inpatient reference tests dropped by half, with costs taking a similar plunge. On the outpatient side, volume dropped about 15 percent, while costs fell by about 25 percent.

Eventually the practices for reference lab testing spread to the entire testing menu, overseen by a laboratory diagnostics committee. A formulary similar to that for pharmacies was installed, with the more esoteric tests attached to medical necessity and efficacy. An insurance-style tiered system was also introduced that divided the tests into three "buckets" that went from common tests any physician could order, to more exotic tests that were restricted to specialty physicians on the URMC faculty, to tests deemed to have questionable effectiveness and required to have committee review and approval. An appeals system was set up for clinicians to make their case if a more costly esoteric test was turned down.

Tier one volumes dropped about 10 percent while costs dropped about 15 percent, tier two volumes dropped about 11 percent while costs dropped about 30 percent, and tier three volumes dropped about 40 percent while costs dropped by about a third.

Levy noted that it helped that the University of Rochester system has a "good collegial environment," which assisted with the implementation, suggesting that overcoming fractious relationships is one key to putting a lab formulary into place.

Quest Obtains CAP Certification for Biorepository

The College of American Pathologists (CAP) has certified a biorepository for Quest Diagnostics.

Quest's 20,000-square-foot biorepository is based in a suburb of Los Angeles. It maintains a collection of tissue, blood, and urine specimens that are no longer identified with a specific patient. The collection is used by biopharmaceutical and biotech firms for the development of new drug treatments and therapies.

CAP launched its biorepository accreditation program in 2011. It only accredits facilities that store samples for the purpose of research, not transplantation. The three-year certification occurs after an on-site inspection by a CAP-trained pathologist, a biorepository manager, or the holder of a doctorate degree. A CAP spokesperson said 14 sites have been accredited, with 17 in various stages of the accreditation process.

"Maintaining the integrity of specimens for molecular and genetic research is particularly important given the fragility of these materials. Our participation in CAP's accreditation program demonstrates our commitment to help our clinical trial and academic collaborators generate the quality research needed to drive medical discovery and innovation, particularly for personalized therapies based on genetic or molecular factors," said Christopher C. Fikry, M.D., vice president of Quest's diagnostics clinical trials division. "Although biospecimens are increasingly used in new drug and companion diagnostic development, a lack of standards to promote quality can jeopardize the reliability of data generated through clinical trials."

The notion of monitoring and accrediting biorepositories in the United States is fairly new. A report by the National Academies Press earlier this year observed that "only in the recent past have the traditional practices of pathologists and their institutions regarding the use of stored specimens for research and education come under scrutiny," most notably a 1999 report by the National Bioethics Commission regarding its recommendations on the ethical uses of human tissue.

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—Christopher C. Fikry, M.D., vice president, Quest Diagnostics clinical trials division

Bruce Friedman, M.D., president of the Pathology Education Consortium, observed that having uniform accreditation and ethical practices will allow pathology labs to appropriately use the specimens they have on hand for research purposes.

■ **Bio-Reference Earnings Barely Dinged by Sandy**, *from page 1*

in a statement. "Revenues were impacted by the shutdown of businesses in the area and the difficulties in moving samples into the area. However, all samples received by the laboratory were processed and results delivered."

For the full 2012 fiscal year, Bio-Reference reported net income of $42.2 million on revenues of $661.7 million. That compares to net income of $36.4 million on revenues of $558.6 million—increases of 16 percent and 18.4 percent respectively.

Meanwhile, the company sought to minimize the impact of the Centers for Medicare and Medicaid Services' recent decision to cut the technical component of surgical pathology billing code 88305 by 52 percent.

"Based on 2012 billings, the company's total 88305 billings to Medicare were less than seven-tenths of 1 percent of total billings, and the reduction to net income in 2012 based on the 2013 rates would have been just under two-tenths of 1 percent of net income," said Bio-Reference Chief Executive Officer Marc C. Grodman, M.D.

For fiscal 2013 guidance, Grodman estimated Bio-Reference would grow net income by about 20 percent and revenues by about 15 percent.

InvivoScribe Creates Genetic Testing Middleman Firm

San Diego-based molecular medicine test firm InvivoScribe Technologies has launched an affiliate company that will permit physicians and genetic counselors to order genetic testing online through a variety of laboratories.

> ***"In order to make personalized molecular medicine a clinical reality, new platforms need to be developed for the delivery of health care."***
> ***—Bradley Patay, M.D., chief executive officer, Genection***

Known as Genection, the company operates through an Internet portal that allows physicians to order tests remotely. It has established relationships with a number of national and regional laboratories, including Salt Lake City-based ARUP Laboratories, genomic cancer testing firm Foundation Medicine in Cambridge, Mass., and two San Diego-based firms: CypherGenomics and the Laboratory for Personalized Molecular Medicine.

"In order to make personalized molecular medicine a clinical reality, new platforms need to be developed for the delivery of health care. Genection's mission seeks to accelerate this adoption process," said Bradley Patay, M.D., Genection's chief executive officer. "The combination of CLIA-validated genetic testing, whole-exome or whole-genome sequencing, and broad targeted assays, along with critical bioinformatics, analytic tools, and interpretative guidelines, will contribute to timely definitive diagnoses for patients with rare, unexplained diseases or complex diseases. In essence, this integration will speed delivery of genomic test results and improve patient care."

Patay added that "clinicians spend too much of their time identifying and ordering clinically relevant genetic tests, while struggling to keep abreast of the flood of clinical information around new biomarkers."

Tests are available in 27 specialties, including internal medicine, pathology, pediatrics, clinical pharmacology, and radiology. The focus is on 16 different diseases and disorders, including infectious and parasitic conditions, blood and lymphatic, respiratory, occupational injuries, and poisonings.

Physicians have the opportunity to select tests both by the laboratory offering them and by price. Genection collects and delivers samples. The company does not work directly with insurers and requests payments at the time of specimen delivery. Test results are posted online and added to the patient's cumulative medical record in the Genection portal.

A company spokesperson did not respond to repeated requests for comment regarding projected test volumes, number of tests being offered, or number of employees working for Genection.

Saint John's Health Center Puts Genomic Pathology Facility on Hold

The management and governance shakeup at a Los Angeles-area hospital likely means the delay of a planned molecular pathology institute.

Lou Lazatin, the former chief executive officer of 265-bed Saint John's Health Center in Santa Monica, Calif., was dismissed on Nov. 30, as was its chief operating officer, Eleanor Ramirez. Many members of the hospital's governing board were also let go by the hospital's parent company, the Sisters of Charity of Leavenworth Health System in Denver.

Although the dismissals took many by surprise, Saint John's had posted losses approaching $35 million over the past two years, while patient revenue was slipping. Sisters of Charity has appointed an acting CEO and COO while it searches for permanent replacements.

On the drawing board for Saint John's was a molecular pathology institute primarily bankrolled by biotech billionaire Patrick Soon-Shiong, M.D., who has committed about $100 million for advancement of the hospital's research facilities. Soon-Shiong told the *Los Angeles Times* that the institute was now on hold.

"I will be evaluating our options over the next two months and having discussions with other partners in the city," he told the newspaper. "I was very disappointed and aghast that the board was not, to my knowledge, consulted and that people who have dedicated their lives to helping others were treated in this way. I am really not sure of the motivations of this new leadership team."

A Saint John's spokesperson declined to comment, while a spokesperson from Soon-Shiong's company, NantWorks, did not respond to request for comment.

NantWorks and its affiliated research institute announced in October it had developed a new process that conducts genomic analysis of an individual patient's cancer in less than one minute.

INDUSTRY BUZZ

Phoenix Children's Hospital Launches Molecular Medicine Lab

The Phoenix Children's Hospital has formed an institute of molecular medicine, noting a relative lack of such research in the area of pediatrics. The institute will have a staff of 50, including scientists and support employees.

"Our goal is to bring genomics research to the forefront of pediatrics," said Robert L. Meyer, Phoenix Children's chief executive officer. "Research and development of novel treatments for pediatric diseases has fallen short over past decades."

Meyer cited recent research from the National Heart, Lung and Blood Institute noting that 70 percent of all medications prescribed to children had only been tested in adults. "We also must address a fundamental flaw in traditional and personalized medicine—diagnosis and treatment of a disease based on clinical instead of genomic information," he noted.

The hospital has recruited two prominent physicians to co-chair the new institute: Timothy Triche, M.D., is a professor of pathology, cancer biology, and pediatrics at the Keck School of Medicine at the University of Southern California and director for personalized medicine at Children's Hospital Los Angeles. Robert Arceci, M.D., is the director of pediatric oncology, Johns Hopkins School of Medicine in Baltimore.

Laboratory space for the institute is being provided by the Translational Research Genomics Institute (TGen) a nonprofit research venture with ties to the University of Arizona and the Van Andel Research Institute in Grand Rapids, Mich. Daniel Von Hoff, M.D., TGen's director of translational research for TGen, will collaborate with Arceci and Triche.

"The institute is a critical piece in the development of our campus and the emerging academic medical center in Phoenix," said Stuart D. Flynn, dean of the University of Arizona's College of Medicine. "This program will catalyze Phoenix Children's Hospital and our region to become national contributors and leaders in molecular medicine."

The institute's initial funding is via a gift from Ronald Matricaria, the former chief executive officer of the biotechnology firm St. Jude Medical, as well as a $1.25 million gift from the Virginia G. Piper Charitable Trust. The remainder of the institute's operations will be funded through other philanthropic contributions and from grants, officials said.

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Coalition for Excellence in Medication Monitoring
202-457-6055

College of American Pathologists
800-323-4040

Genection
858-224-6666

Partners Health Care
617-278-1000

Phoenix Children's Hospital
602-933-1000

Quest Diagnostics
800-222-0446

Saint John's Health Center
310-829-5511

Translational Research Genomics Institute
602-343-8400

University of Rochester Medical Center
585-275-8762

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Kimberly Scott, Managing Editor, kscott@G2Intelligence.com; Ron Shinkman, Editor; Heather Lancey, Designer; Beth Butler, Marketing Director; Dan Houder, COO and Publisher
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