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LABORATORY INDUSTRY REPORT™

Vol. 14, Iss. 11, June 5, 2014

HIGHLIGHTS

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OpGen Releases Molecular Test for Hospital-Acquired Infections

OpGen, the Maryland-based clinical laboratory, has released a new molecular-based test that can identify patients at risk for harboring microbes that are highly resistant to antibiotics.

The test, known as Acuitas, can be used to screen patients as they are admitted into hospitals and other care settings to ensure they do not spread difficult-to-control infections. Samples are taken with perio-anal swabs. OpGen can also test cultural isolates gathered by hospital infection control personnel.

Altogether, Acuitas can detect seven genes that are directly involved with a variety of hospital-acquired infections (HAIs), including KPC, NDM, VIM, IMP, CTX-M, VanA, and OXA. Those genes are directly linked to carbapenem-resistant enterobacteriaceae, extended-spectrum beta-lactamase, and vancomycin-resistant enterococcus. It can detect 200 different subtypes within those genes.

"Drug-resistant 'superbugs' pose a serious and immediate threat to the world's health and safety, increasing the likelihood of prolonged illnesses, higher costs—even death," said Evan Jones, OpGen's chief executive officer.

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XIFIN, PAML Spar Over Contract That Went Sour

As 2012 drew to a close, XIFIN Inc. entered into a lucrative contract to help manage the billing for Spokane, Wash.-based PAML. But not long after the San Diego-based firm headed north to begin the work, the whole pact began to go south.

As a result, the two high-profile firms briefly duked it out in a very public manner, with XIFIN suing PAML in federal court, claiming it breached a multimillion-dollar contract, acted in bad faith during the course of the contract, and defamed it to another potential client.

However, XIFIN and PAML apparently reached a settlement earlier this week. A statement issued by a XIFIN spokesperson late on June 4 declared that the two sides "have had productive meetings and found an amicable way forward. Both companies continue to have

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OpGen Releases Molecular Test for Hospital-Acquired Infections, *from page 1*

One of the biggest selling points for the Acuitas assay is its turnaround time—the test can be performed at OpGen's lab in Gaithersburg, Md., and results generated and transmitted within 24 hours. That compares to the current culturing and testing method of suspected infection sites that can take three or four days.

Molecular testing for HAIs is a relatively new approach, but it is also being undertaken by hospital labs as well as stand-alone facilities. John T. Mather Memorial Hospital in Port Jefferson, N.Y., uses molecular testing to detect methicillin-resistant Staphylococcus aureus, better known as MRSA. The $25 test was able to drive down the rate of MRSA infection at the hospital from 14.8 cases per 1,000 discharges to 1.1 per 1,000 within three years of assaying patients.

HAIs are a bane of the health care industry. A study published by Harvard University researchers last year concluded that HAIs cost the United States $10 billion a year, with most forms of the condition costing anywhere between $11,285 to more than $45,000 per patient to treat. The Centers for Disease Control and Prevention estimates that there are about 2 million cases of HAIs annually, a number many experts believe is underreported.

The retail cost of an Acuitas test is less than $100, according to an OpGen spokesperson. OpGen declined to disclose projected volumes for Acuitas.

Takeaway: The need to combat superbug infections in the hospital setting is driving new lab tests and speeding up turnaround times. G2

Smaller Genomic Labs Are Struggling

Although many publicly traded genomic laboratories are experiencing extraordinary growth in their revenues, smaller organizations are reporting decidedly mixed results, including struggles keeping their revenue streams in place.

Florida-based OPKO Health reported revenue of $22.3 million for the first quarter, down nearly 30 percent from the $31.3 million reported during the first quarter of 2013. Its net loss widened to $45.1 million, compared to $34.6 million during the year-ago quarter.

Company officials attributed much of the increased loss to an additional $11 million devoted to expanding product research and development, especially in relation to its 4Kscore prostate test, which was released on March 31. Phillip Frost, M.D., OPKO's chief executive officer, said the new test was expected to generate substantial revenues in the months ahead. OPKO's stock rose about 3 percent in trading on the New York Stock Exchange the day after earnings were announced and has risen another 5 percent since then.

Massachusetts-based Interleukin Genetics appears to be stuck in place. Its first-quarter revenues were $488,000. Its first-quarter 2013 revenue: $487,000. It lost $1.7 million during the quarter, up about 40 percent from the first quarter of 2013. The company has developed and markets genetic tests to predict periondontal disease and tooth loss, as well as predicting the best exercise regimens for weight loss. Interleukin received approval from New York regulators in April to

offer its periodontal disease test in that state. It receives reimbursement of $125 to $200 per periodontal test, Chief Executive Officer Ken Kornman told analysts during a conference call to discuss earnings.

Meanwhile, Nebraska-based Transgenomic is having trouble maintaining its ground. It reported a net loss of $4.2 million for the first quarter, compared to a loss of $3.6 million during the first quarter of 2013. Revenue declined to $6.3 million from $7.4 million, a drop of 15 percent. Chief Executive Officer Paul Kinnon said he was buoyed by the quarter-over-quarter growth in its laboratory services segment. It grew from $2.8 million during the fourth quarter of 2013 to $3.7 million in the most recent quarter. However, it was still down 17 percent from the $4.4 million reported for the first quarter of 2013.

"This is where we see the best prospects for substantial, sustained, profitable growth in the near and midterm, and this increase in sequential sales is an early but promising sign that our rebuilding efforts are on track," Kinnon said.

Takeaway: The smaller genomic laboratories are struggling with growing revenues and narrowing losses.

Foundation Medicine Pushing Overseas Expansion

Although still a relatively small enterprise, Foundation Medicine has begun a big push to distribute its products overseas.

The company has appointed a vice president in charge of international development. Urmi Prasad Richardson, who previously held executive positions with Chiron, Novartis, and Immucor, is based in Germany.

Meanwhile, the Massachusetts-based firm has struck a deal with the Spanish firm Laboratorios LETI for the distribution of its tests to physicians in Spain and Portugal. The availability of the test represents a significant technological expansion of the offerings by the Barcelona-based Laboratorios. Its diagnostics division has been heavy on basic tests such as assays for detecting HIV, respiratory tract infections, and diabetes.

In addition to the deal with Laboratorios, Foundation Medicine has also obtained a CE mark to distribute its tests throughout the rest of Europe.

"We are very pleased to have received a CE mark and look forward to expanding the availability and adoption of FoundationOne to customers in the European oncology community," said Kevin Krenitsky, M.D., the company's chief commercial officer and senior vice president of international strategy.

Foundation Medicine officials said that it has issued reports to clinical customers in more than 40 nations outside of the United States. It offers two molecular assays, FoundationOne for solid cancer tumors, and FoundationOne Heme for hematologic malignancies, sarcomas, and pediatric cancers. Genomic profiling of the cancers makes for more close matches to targeted drugs and clinical trials.

Takeaway: Even as it remains in the quick growth stage in the United States, Foundation Medicine is making an aggressive push for market share in Europe.

More Labs Turning to Data Analytics To Improve Operations and Population Health

Data analytics took baseball by storm a little more than a decade ago. It is among the reasons why the perennially broke Oakland Athletics contend for a pennant nearly as often as the cash-laden New York Yankees.

The trend of using software to minutely crunch numbers is now beginning to take hold in places where chemistry is something that occurs at a test bench rather than in a clubhouse. In the lab setting, data analytics is being used for issues ranging from operational tweaks to population health initiatives, and it is creating a boon for the companies that offer suites that focus specifically on lab operations.

Viewics, a California firm that was formed only five years ago, has seen its client roster increase about sixfold over the past 18 months and its workforce multiply fivefold over the past year. It offers a variety of software products specifically aimed at clinical laboratories and anatomic pathology practices.

> ***"I would assume all labs all do basic [analytics] at this point."***
> ***—Shahrzad Grami, Data and Processing Manager, Health Diagnostic Laboratory Inc.***

"They're one of the couple of big players in the lab space," said Barry Portugal, president of Health Care Development Services Inc. in Nokomis, Fla. "They offer exceptionally valuable information." He also mentioned that another big player is Visiun Inc. in Ann Arbor, Mich.

Portugal's firm began offering benchmarking data for laboratories back in the mid-1980s, but with personal computing just in its infancy, most of the number crunching occurred via written questionnaire.

Financial, Operating Environment Creates Need

According to Portugal, the need for rapid data analytics has become critical in the lab space. The reasons are numerous, but the biggest one is reimbursements are continually being ratcheted down or moved from fee-for-service to managed care rates by both government and private payers and the growth of accountable care organizations. In such an environment, the demand for actionable information that can make an operation more efficient and therefore improve the bottom line has grown tremendously.

Moreover, the operational dynamics of labs have also changed.

"You have hospital consolidations that result in lab integrations, with many different testing platforms, and you can do far more tests on a single machine than you could in the past, while the number of machines has decreased," Portugal said.Yet just five years ago, the vast majority of hospital labs could not calculate the cost of performing a specific test.

That approach appears to be changing rapidly. "I would assume all labs all do basic [analytics] at this point," said Shahrzad Grami, a data and processing manager for Health Diagnostic Laboratory (HDL), a firm itself that barely existed five years ago.

The Richmond, Va.-based HDL, which performs about 200,000 tests daily, uses data analytics to determine if its test platforms are operating at peak effectiveness and to study ordering trends among clinicians for its new tests, among other uses. "I've seen decisions change" as a result of studying the order data, Grami observed.

Rapidly scrutinizing provider behavior is one of the benefits of using data analytics. "If a physician or customer is exhibiting odd behavior and their ordering volume has dropped off 30 percent all of a sudden, this is a good way to get in front of the issue and talk with them before they go off to [another lab]," said Tim Kuruvilla, Viewics's vice president of sales and marketing and one of the company's co-founders.

Viewics's software does more than that, however. It allows users to determine times of day when test arrivals are at their peak in order to schedule employees more efficiently. It can help weed out errors in the ordering or testing process and can also determine how long it takes to process a specific test.

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—Tim Kuruvilla, Vice President of Sales and Marketing, Viewics Inc.

Cottage Health, a three-hospital system in the Santa Barbara area of California and one of Viewics's customers, used to have a member of its IT staff devote about half of their time to pulling out data and creating reports just for Pacific Laboratory Services, its in-house lab. Now, they spend perhaps 5 percent of their time on that task.

Portugal noted that one of his clients, a multihospital system in the Midwest, used data analytics to determine the level of productivity at its labs and found vastly differing levels between them.

"By employing the analysis of their lab data analytics, they were able to reduce staff by at least three to four [full-time employees] by changing their workflow. They would not have been able to do that in the past," he said.

Data analytics are also useful in reducing unnecessary and duplicative testing, as well as blood management. In some instances, large hospitals or hospital systems can reduce their blood use by 20 percent or more and potentially save millions of dollars a year, according to Portugal.

Also Useful for Population Health

Data analytics can also be used for population health measures, which in turn can be used to demonstrate the "value-over-volume" paradigm shift being experienced by the laboratory sector.

HDL, for example, uses data to rate the health of the patients being treated by the physicians who purchase their testing services, which focus primarily on wellness measures. The doctors receive an annual report that compares the health levels of patients being treated by one physician in a practice versus another, using the lab's well-known green/yellow/red reporting metrices.

"We want to give them a sense of how they're doing," Grami said.

Another example of how this is being used is at the Joint Venture Hospital Laboratories (JVHL), a network of more than 120 hospital-based laboratories in Michigan and Ohio. JVHL collaborated with Medivo, a New York City-based laboratory data analytics firm. They focused specifically on 75,000 diabetic patients and their frequency of testing for blood sugar levels, and used testing data to construct the management climate for the disease.

"We're trying to look at data that drives accountability."
—John Kolozsvary, Executive Director, Joint Venture Hospital Laboratories

The rate of noncompliance at the start of the collaboration ranged between 54 percent and 74 percent, depending on the physician group, and only about a third received proper follow-up care based on American Diabetes Association guidelines.

Although JVHL has been providing data to its members since it was formed in the mid-1990s, it is beginning to put it together and present it in a way that would compel improved health among the patients who are being tested.

"We're trying to look at data that drives accountability," said John Kolozsvary, JVHL's executive director. However, Kolozsvary added that JVHL has yet to reach a level of granularity that would allow its members to create ground-shaking operational efficiencies.

For those labs that do decide to use data analytics, it is not an inexpensive move. Although Kuruvilla said that pricing ranged widely depending on laboratory size and that Viewics' pricing is structured as a subscription and does not require capital costs, he did not disclose specific numbers. Portugal said installing a suite and reporting dashboards runs between $40,000 and $150,000.

As a result, Portugal noted that lab executives need to make sure that employing data analytics to improve the bottom line should be focused on operational, service, and financial performance elements.

In other words, Moneyball for the national pastime, and money for the laboratories.

Takeaway: Data analytics can potentially be used to streamline laboratory operations and improve the bottom line, as well as help prove the value-versus-volume case that needs to be made to both payers and providers. G2

■ **XIFIN, PAML Spar Over Contract That Went Sour**, *from page 1*

great respect for each other's high quality products and services. This respect and collaboration has allowed PAML and XIFIN to resolve the issues that were the subject of litigation."

XIFIN had previously claimed that PAML only paid it $700,000 out of a minimum of $5.7 million it was owed for the pact and that PAML systematically delayed providing the information required for XIFIN to install the billing system.

"PAML's executive leadership did not provide guidance and staff prioritization or make the decisions needed to implement the implementation project plan, and PAML IT did not perform or did not timely perform the PAML obligations in the agreed upon . . . plan," the lawsuit had claimed.

The lawsuit claimed that PAML's recalcitrance was due in part to the hiring of a new chief financial officer and chief information officer not long after the contract was signed, and neither was onboard with working with XIFIN.

The suit also had claimed that PAML executives asked that XIFIN program its software in a way that it would no longer be compliant with state and federal guidelines. XIFIN alleges that was in contravention to a request by PAML Chief Executive Francisco Velázquez, M.D., that it be compliant with both federal and state rules.

Eventually, the suit claimed, PAML's executives realized it was not going to meet implementation deadlines and, as a result, "compile[d] an exhaustive list of all pending implementation details, or issues that PAML didn't understand about the XIFIN system, label[d] them as 'material breaches,' then harass[ed] XIFIN, by sending multiple letters from counsel, articulating an ever changing list of implementation details as material breaches" to the contract. Eventually, PAML claimed 98 instances of breaches to the contract, according to the suit.

XIFIN had claimed in the suit that it made attempts to address PAML's concerns, but the lab showed little concern whether the breaches it claimed had occurred were fixed or not. The suit also claims that in December of last year, PAML's chief financial officer defamed XIFIN to another potential client, Integra Imaging, by telling an executive with that firm that PAML had to push back implementation deadlines due to XIFIN and that XIFIN's products would likely not meet its needs. According to XIFIN, it believed it was the top candidate for a contract with Integra, and it never received the company's business. PAML formally terminated the contract on March 3 of this year, the suit claimed.

Founded in 1997, XIFIN has grown into one of the largest financial intermediary and revenue management firms for laboratories in the United States. PAML is one of the largest independent labs in the western United States.

Neither Velázquez nor XIFIN Chief Executive Officer Lâle White were available to discuss the litigation and apparent settlement.

Takeaway: Service contracts between laboratories and other firms do not always go smoothly as originally envisioned. G2

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INDUSTRY BUZZ

Sloan-Kettering Opens Center for Genomic Oncology

A legendary investment banker and his wife have granted $100 million to Memorial Sloan-Kettering Cancer Center to create an initiative to systematically analyze every patient's cancer at the genomic level.

The Marie-Josée and Henry R. Kravis Center for Molecular Oncology occupies about 5,700 square feet of newly renovated laboratory space in Memorial Sloan-Kettering's Zuckerman Research Center. Henry Kravis, a co-founder of Kohlberg Kravis Roberts & Co., has a personal fortune approaching $5 billion.

The center has about 100 employees, including some current lab investigators. Staff will use the Memorial Sloan-Kettering-developed assay, the integrated mutation profiling of actionable cancer targets, or TARGET, for screening purposes, among other diagnostic tools. TARGET can screen for mutations in 341 separate cancer genes.

"Progress in our understanding of the biology of cancer has completely shifted the way we think about and treat cancer," said Craig Thompson, M.D., Memorial Sloan-Kettering's president and chief executive officer. "We're moving away from the concept of treating cancer as many different types of the same disease and toward treating each person's cancer as its own unique disease."

The center's goal is to analyze at least 10,000 cancer tumors during its first year of operation and eventually offer genomic analysis of every kind of cancer. It plans to enroll patients into narrow phase one clinical trials known as basket studies in order to offer them medications based on the specific genetic mutations. It will also study patients known as "exceptional responders"—those who react positively to a medication that did not work for most other patients. In the past, Memorial Sloan-Kettering performed whole-gene sequencing on a patient with advanced bladder cancer who had an exceptional response to the drug Afinitor. This led to the discovery of a mutation in the TSC1 gene, which now allows for the targeted use of Afinitor.

"Our integrated clinical and scientific teams coupled with our ever-increasing genetic sequencing capabilities will allow us to build upon the molecular insights we've gleaned over the past decade to accelerate the development of more effective and less toxic cancer therapies," said David B. Solit, M.D., the center's director.

Takeaway: A single large donation could push progress in genomic oncology.

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Health Diagnostic Laboratory
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Interleukin Genetics
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June 5, 2014 www.G2Intelligence.com

 Laboratory Industry Report (ISSN 2332-3884) is published by G2 Intelligence, 24 Railroad Street, Keene, NH 03431-3744 USA. Tel: 800-531-1026. Fax: +1-603-357-8111. Web site: www.G2Intelligence.com.

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