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HunterHeart, BioReference Clash Over Details of 2013 Transaction

Chris Riedel, the often litigious laboratory entrepreneur, has taken on the lab that purchased a large part of his business interests in 2013, and that lab is fighting back.

Although Riedel sold Hunter Laboratories to BioReference Laboratories 18 months ago, he retained control of HunterHeart, a former affiliate that focuses on cardiac testing. That lab has filed suit against BioReference, claiming that it breached its purchase contract of Hunter Laboratories and interfered with HunterHeart's business.

According to the suit which was filed in Santa Clara County (CA) Superior Court last August, BioReference had agreed to provide HunterHeart with testing services and reports for six months after the

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Boston Heart Diagnostics Offers Graphically Rich, Personalized Test Reports

Although personalized medicine remains a growing niche in health care delivery, it is also hotly competitive. Many specialty laboratories painstakingly hone their products in order to attract the attention of patients and clinicians who may be on the fence about using it.

Boston Heart Diagnostics has invested a couple of years and millions of dollars in its new cardiovascular health report that it hopes will spur both patients and their doctors to order its assays.

Simply called the Diagnostic Report, it runs 25-plus pages and its graphical interface is well beyond that of the typical laboratory report. It refers to the patient by their first name and focuses on four areas specific to them: Their lipids, inflammation, metabolics and genetics. Pages are dominated by large drawings of the human circulatory system and coronary artery cutaways in order to discuss various vascular conditions and how it impacts the patient. The text contains straightforward metaphors, such as comparing the patient's coronary arteries to plumbing in their home (plaque replaces grease, the arteries representing metal pipes and the blood the home's flow of water).

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Boston Heart Diagnostics, *from page 1*

If the cardiac testing indicates that the patient is at risk, it will say that the patient is in danger "because you have a high risk of forming a blockage that can lead to a heart attack or a stroke." Test results, such as cholesterol and triglyceride levels, are inserted into a slide-like graphic labeled "good," "caution," or "danger." A section called "where you stand" delves into specifics about that patient's condition, with phrases such as "too much" or "more than you should" or "looking good."

Boston Heart Chief Executive Officer Susan Hertzberg said the new report has been a part of her overall plan since she arrived at the Massachusetts-based company five years ago.

"Most patients don't even get their lab reports, and when they do, it's a bunch of numbers and (letters)," Hertzberg said, adding that such hazy data is among the reasons 30 percent of patients with high cholesterol levels don't refill their statin prescriptions after the first regimen and 60 percent don't refill it after the first year. "Contextualizing information has been a goal of mine."

Peter Francis, president of Clinical Laboratory Sales Training, a Maryland-based consulting firm, believes the report offers some advantages. "The Boston Heart report appears very easy for anyone to understand—and that may be their sales 'hook.' It's not cluttered with a variety of sub-particle HDL and VLDL statistics [offered by] other heart labs." Francis added that having a report with simple graphics and straightforward explanations can also improve communications between physicians and their patients.

That's what Hertzberg would prefer. She noted that the report was designed specifically to better inform patients and create dialogues with their caregivers. "What's driving disease rates in this country are the way we eat, the way we sleep, lack of exercise. And unless we take a more holistic approach and replace some fear with optimism, it's not going to change."

Along with the test results, the report also offers suggestions on how patients can improve their readings, including advice on improving their diets and level of exercise. Boston Heart also offers coaching with dietitians in order to prompt patients to make the lifestyle changes that can improve their health.

Of course, Hertzberg also sees the company benefiting from the new report, which will be used to pitch the company's testing services through its existing pipeline of about 70 sales representatives. Although it has grown from about $2 million in annual revenue when she came on board in 2010, to about $95 million today, Boston Heart provided testing services for about 500,000 patients last year. The fact that coronary vascular disease is pretty much endemic in the United States means Boston Heart has far more upside growth potential.

"We see this as offering an integrated value proposition to the doctors treating these patients," Hertzberg said.

Takeaway: Boston Heart Diagnostics is pushing graphical representations on its lab reports to better involve the patient in improving their cardiac health.

Trovagene Collaborates With UC San Diego on Lung Cancer Diagnostics

Molecular laboratory Trovagene has entered into a collaboration with the University of California at San Diego that could eventually lead to a blood-based diagnostic test for some forms of lung cancer.

The collaboration, which involves the university's Moores Cancer Center, will focus on the clinical utility of monitoring mutations in genes connected with the epidermal growth factor receptor, or EGFR. Such mutations have been traced to patients with non-small cell lung cancer.

"A liquid biopsy has potential to reduce the need to conduct lung tissue biopsies, and also offers the ability to frequently obtain critical genomic information for improved patient management."

— Hatim Husain, M.D. Lead investigator and assistant professor of hematology-oncology at UC San Diego Moores Cancer Center

Although patients with this form of the disease are often given EGFR inhibitors as part of their treatment regime, the cancer still often progresses, suggesting that a more specific focus on mutations is required in order to fine tune medications.

The development of such a test could be crucial in treating the disease, which has an average five-year survival rate of around 25 percent, including all stages of lung cancer. That's primarily because lung cancer is usually detected late in its progression—typically after it has become symptomatic. The survival rate is higher the earlier it is diagnosed but at stage two of the disease, the survival rate drops to around 30 percent and drops rapidly in subsequent stages. The survival rate from the small cell version of the disease—which completely lacks any molecular-based diagnostic test—is even lower.

Both Trovagene and UC San Diego officials are hoping to be able to create a test that could detect the presence of non-small cell lung cancer without requiring a biopsy, an involved and often painful procedure.

"A serious clinical challenge in treating this disease is to obtain lung tissue biopsies. Severe complications from these biopsy procedures occur and are associated with significant cost," said Hatim Husain, M.D., lead investigator and assistant professor of hematology-oncology at UC San Diego Moores Cancer Center. "A liquid biopsy has potential to reduce the need to conduct lung tissue biopsies, and also offers the ability to frequently obtain critical genomic information for improved patient management."

Trovagene has developed a testing platform for detecting mutations in patient-specific cancers. It has conducted similar collaborations and studies on lung cancer patients with Memorial Sloan Kettering Cancer Center in New York City and City of Hope National Medical Center in Southern California. Company officials said the collaboration with UC San Diego would constitute an expansion of the work with those other hospitals.

Takeaway: Trovagene is continuing to develop testing techniques in collaboration with academic medical centers to hone treatments for cancer patients.

Inside The Lab Industry

In-Office Testing Continues to Grow at Rapid Pace

Despite the ever-growing offerings of exotic molecular tests and the resumption of stronger volumes for national laboratory giants Quest Diagnostics and LabCorp, in-office medical testing remains a robust component of the laboratory sector. And data suggests it's only going to continue getting bigger.

"Some of these retail clinics are integrating their (test results) and physician office access into their business models, which is also causing on-site testing to rise."

— Robert Gregory, Chief Business Officer, Atlas Medical

The growth of in-office testing—also known as point-of-care tests—is being driven by a variety of factors. They include a boom in toxicology testing (which can often be performed with a relatively straightforward urine assay), a continued drop in prices and increasing sophistication of the technologies required to produce and perform such tests, and the desire of small to medium-sized medical practices to earn money on an ancillary service--particularly as they're being squeezed by government and commercial payers by the other services they perform. Point-of-care testing also seems to sit well with the American ethos of do-it-yourself independence and the potential for reaping commercial gains.

However, other entities aside from physician offices are getting into the point-of-care game. That includes outpatient and community clinics and retail clinics operated by national drugstore chains such as CVS.

"Some of these retail clinics are integrating their (test results) and physician office access into their business models, which is also causing on-site testing to rise," said Robert Gregory, chief business officer for Atlas Medical, a California-based consulting firm that focuses on coordinating diagnostic services.

But the trend in point-of-care testing is also bumping up against some other issues, such as the Food and Drug Administration's move to try to more closely regulate some facets of testing, the consolidation of medical practices, and a desire by the provider community to try and aggregate patient data into a single electronic health record.

Nevertheless, in-office testing was a $2.44 billion market worldwide in 2014. The U.S. accounts for 58 percent of that market, even though it represents only about 5 percent of the global population, according to the Maryland-based research firm Kalorama Information. By contrast, Europe accounts for less than a third of the overall market. Meanwhile, the U.S. market is growing at a compounded annual growth rate of 4.5 percent, compared to 1 percent in Europe and 1.6 percent in Japan.

Inside The Lab Industry

"The United States is the center of the physician office lab trend," said Kalorama Publisher Bruce Carlson.

According to a Kalorama report published last year, "one multispecialty practice in the Midwest with 40 physicians has a lab that does 500,000 tests each year, including moderate and high-complexity tests ... the practice runs an average of 250 patients during a day and employs seven full-time technologists (and) seven phlebotomists."

Peter Francis, who runs a Maryland-based laboratory consulting firm, noted that many hematology and oncology offices perform complete blood count testing in-house, primarily because of the need for a rapid turnaround while the patient is still present. But the capabilities of some of the point-of-care tests have given him pause. "I once uncovered an OB/GYN in Rockford, Ill. that was performing Affirm III in his office," he said, referring to a complex molecular test for vaginitis that most physicians typically send out to a reference lab. "I remember being shocked at the time of seeing this in-house capability—I had never witnessed it before," he added.

Some Top In-Office Tests, Ranked By Estimated Volume, 2014

1. Dipstick Urinalysis

5. Strep A Antigen Rapid Test

10. Glucose (fingerprick)

20. Hematocrit

25. pH body fluids

Source: Kalorama Information

Francis noted that there are also some in-office arrangements that are far less complex and are intended primarily to capture extra revenue. That would include a dermatology or dermopathology practice setting up a technical component lab that bills for preparing slides that are then sent out for interpretation.

Despite the delicacy of such arrangements, the physical nuts-and-bolts of point-of-care testing remain fairly simple. They often avoid complications such as the use of multiple reagents or wet chemistry handling. And if they are required, such steps are sometimes compressed into disposable cassettes or cards.

As a result, assays in this realm are usually waived under CLIA regulations, meaning they're minimally regulated. That typically includes such tests as urinalysis, hormone tests, and rapid assays for diseases such as HIV or hepatitis. On average, about 650 such tests per year have been waived under CLIA between 2010 and 2013—mostly for drug abuse testing and urinalysis, according to data compiled by Kalorama.

Whether the FDA's recent move to regulate laboratory developed tests will affect that specific market remains to be seen. The American Clinical Laboratory Association and other laboratory lobbies have objected to any regulation of

Inside The Lab Industry

"Labs performing LDTs likely already have high-complexity CLIA certification. On the other hand, point-of-care diagnostics, at least in the U.S. and particularly in the case of physician offices and near-patient testing, is heavily reliant upon the 'dumbing down' of established ... tests."

— Emil Salazar, Kalorama analyst

LDTs, suggesting instead that a tightening of CLIA regulations would suffice instead. However, it seems unlikely that this would impede the granting of waivers for the point-of-care market because such tests usually don't impose grave risks on a patient if they're misapplied or misinterpreted.

"Labs performing LDTs likely already have high-complexity CLIA certification. On the other hand, point-of-care diagnostics, at least in the U.S. and particularly in the case of physician offices and near-patient testing, is heavily reliant upon the 'dumbing down' of established ... tests," said Emil Salazar, a Kalorama analyst who wrote its point-of-care report. "At a certain point, a test is deemed by the FDA to have minimal enough risk on patient health (in the event of an erroneous result and subsequent impact on therapy) and/or low enough risk of user error that it is granted waived status."

The other issue is whether such testing winds up being properly integrated into a patient's overall electronic health record. The Kalorama report suggests that many new point-of-care tests are far more highly connected than in the past, with many able to transmit results directly to desktop or laptop computers. It noted that "continued consolidation in health care systems and mounting pressure to coordinate care and eliminate unnecessary repeat services will encourage greater penetration of connectivity solutions among (testing) instruments and devices."

One of the biggest issues that Atlas' Gregory often encounters is "siloization"—where a test is performed in the physician's office but is not shared with a patient's other providers.

"The physician making ordering decisions must be working with the most current patient information available. Our view is that labs must maintain dynamic access to the most complete set of patient data and make that information available to order makers as part of their workflow at the time they are ordering testing," Gregory said. "The more that 'islands' of data are perpetuated, without the means of integrating that data into the continuum of care, the more likely inappropriate or unnecessary tests will be performed."

Takeaway: In-office/point-of-care testing is continuing to grow at a rapid pace in the U.S., spurred on by market conditions that appear to be unique compared to the rest of the world. G2

HunterHeart, BioReference Clash Over Details of 2013 Transaction, *from page 1*

deal to buy Hunter Labs closed in early August 2013. BioReference also agreed to pay HunterHeart 40 percent of what it had collected. But HunterHeart claimed that BioReference failed to do so and withheld approximately $1.1 million in revenue. It also accused BioReference of holding back another $4 million it still owed as part of the original purchase.

The suit also claimed that when testing was performed on behalf of HunterHeart, BioReference often omitted HunterHeart's logo from the test results and sometimes withheld some test results from patients, damaging its reputation and business.

The publicly-traded BioReference acquired Hunter Laboratories, in part, to expand its book of business on the West Coast and continue its rapid expansion. For its fourth fiscal quarter of 2014, BioReference reported net income of $18.3 million on revenue of $227.6 million. That compares to net income of $11.1 million on revenue of $192.2 million, for fiscal fourth quarter of 2013, increases of 52 percent and 18 percent, respectively. For fiscal 2014, net income was $46.8 million on revenue of $832.3 million. That compares to net income of $45.8 million on revenue of $715.4 million for fiscal 2013. The company has not mentioned the lawsuit in any of its filings with the Securities and Exchange Commission, suggesting it does not consider it to be a substantive issue.

BioReference countersued HunterHeart in late October. It claimed that the company had failed to pay millions of dollars in back income and payroll taxes—including for all of the calendar years 2009 and 2010—and that the $4 million had been held in escrow in order to satisfy such debts. According to its countersuit, HunterHeart never used the money to make the payments, and except for some minimal payments, the tax obligations continue to be unpaid. The countersuit also claims that while HunterHeart had provided correspondence from the Internal Revenue Service that all its taxes were paid, it had still not filed a tax return for fiscal 2013, leaving other debts unsettled.

The countersuit also claimed that Riedel breached a three-year non-compete clause by working with the Los Angeles-area West Pacific Medical Laboratory and attempting to induce some BioReference employees to work for West Pacific. It also claims that Riedel's wife Marcia withdrew cash from HunterHeart accounts for her personal use in the two months prior to the deal closing.

Before selling Hunter Laboratories, Riedel had been the proverbial thorn in the side of many larger competitors, not hesitating to sue them if he believed they colluded to deprive other labs of business. Quest Diagnostics paid $241 million in 2011 to settle a whistleblower suit Hunter Labs had filed against it in California, claiming it had overcharged that state's Medicaid program. LabCorp settled a similar suit that same year for $49.5 million. Riedel continues to pursue similar claims against Quest in other states.

A trial date for the HunterHeart lawsuit has not yet been scheduled.

Takeaway: Although operating in a smaller venue, litigation continues to be very much part of Chris Riedel's modus operandi. G2

INDUSTRY BUZZ

Study Validates Use of Rosetta Kidney Cancer Test—With A Catch

A peer-reviewed study analyzing how urologists treat patients with kidney tumors gives some validation to the use of a New Jersey-based laboratory's genomic for kidney cancer.

The study of more than 100 urologists, published in the most recent edition of the Journal of Kidney Cancer, suggested a majority would use a test distributed by Rosetta Genomics to determine the difference between a benign renal oncocytoma and a renal cell carcinoma, a cancerous malignancy.

Currently, the use of CT scans, ultrasounds and magnetic resonance imaging are the primary tools for determining the presence and significance of renal tumors. However, in many cases, benign tumors are often mistaken for malignant, leading to the complete removal of the affected kidney. That's an option the study concluded 59 percent of clinicians would avoid and 31 percent would instead opt for a partial nephrectomy if they were confident the tumor was benign. Many others suggested they would engage in watchful waiting instead.

Aside from the risks to a patient undergoing surgery, the costs of a complete nephrectomy are far steeper than the alternatives—the mean cost is $11,567 for a total kidney removal and $7,200 for a partial removal, according to the study.

"Clinician receptivity ... to change their practice and increase use of pre-nephrectomy biopsy to reduce unnecessary surgery is a critical first step to improve care and lower health care costs," said Kenneth A. Berlin, Rosetta's chief executive officer. "The results of this survey should significantly enhance our efforts to make pre-nephrectomy biopsy and differential diagnosis ... a standard practice in kidney cancer diagnosis and treatment."

Rosetta has its work cut out for it: Only 9 percent of urologists surveyed say they use biopsies for diagnostic purposes, even though its mean cost is similar to an MRI. Fully a third said undertaking a biopsy was a "major barrier" to using the Rosetta assay, and another 52 percent said it represented a minor barrier. Only 15 percent said it would present no barrier at all.

Takeaway: Rosetta's kidney tumor test could wind up cutting costs for treating renal tumors if clinicians accepted biopsies as a more commonplace practice. G2

References

Atlas Medical
818-340-7080
rgregory@atlasdev.com

BioReference Laboratories
800-229-5227

Boston Heart Diagnostics
508-877-8711

Clinical Laboratory Sales Training
410-299-6562
peter@clinlabsales.com

HunterHeart
408-398-2125

Kalorama Information
800-298-5603
bcarlson@marketresearch.com

Rosetta Genomics
215-382-9000

Trovagene
858-952-7570

UC San Diego Moores
Cancer Center
858-822-6100

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