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HIGHLIGHTS

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Quest, LabCorp Accused of Fraud In Newly Unsealed Suit

A whistleblower lawsuit against the nation's two largest freestanding laboratory businesses was unsealed in U.S. District Court in California earlier this month.

The suit, filed in 2012 by former Quest Diagnostics phlebotomist Elisa Martinez, accuses both the New Jersey-based Quest and North Carolina-based LabCorp of conducting duplicate blood and urine tests for which Medicare and the state of California were billed multiple times.

The lawsuit listed at least four Northern California patients who underwent blood or urine tests. It claimed extra blood was drawn from the patients and their urine samples were "split" in order to perform duplicate assays. Medicare and Medi-Cal, California's Medicaid program, were billed twice. When Martinez asked supervisors why the practice was in place, she was told to stop asking questions and be more supportive of the lab's practices, according to the suit.

Martinez also allegedly learned from a former colleague of hers

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PAML, Cleveland Clinic Labs To Share High-End Tests

The Cleveland Clinic Laboratories and Spokane, Wash.-based PAML, which entered into a semiformal strategic alliance last year, have disclosed the first steps the partnership will take.

PAML recently announced that the two laboratories would perform testing for one another for specific assays on their menus. PAML Chief Executive Officer Francisco Velázquez said the agreement covers "several dozen" tests. The terms of the agreement prohibit Velázquez from disclosing which tests will be shared, although he indicated they were mostly high-end assays that focus primarily on cardiovascular, genetics, and oncology diagnostics, among other specialties.

"We identified areas where we had an opportunity to have better test menus together. What that basically means is the Cleveland Clinic will send testing to PAML, and PAML will send testing to the

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■ **Quest, LabCorp Accused of Fraud in Newly Unsealed Suit**, *from page 1*

at Quest who went to work for LabCorp that that lab also engaged in similar practices, which is why it is also named as a defendant. However, the exhibits attached to the lawsuit involve only Quest. The suit accuses the labs of violating both the federal and California False Claims Act.

Martinez was hired by Quest as a phlebotomist for its patient service center in Red Bluff, a remote Northern California town, in July 2009. She took family or medical leave in February 2011 and was fired in June of that year.

The suit was unsealed under fairly unusual circumstances: Judge Kimberley J. Mueller denied a motion from the U.S. government for a fifth extension of time that would have kept the suit under seal until March 2015. "In this case it appears the government intends to settle the case under seal while stalling with respect to intervening," Mueller wrote in her order to unseal the case, concluding that the government had run out of rationales for extension. Most qui tam cases are unsealed when the government chooses to join forces with the plaintiff, known as the relator.

A trial date for the case has not yet been set.

Both Quest and LabCorp have been accused in past lawsuits of defrauding the Medicaid program in California. In 2011, both settled cases involving allegations of kickbacks paid to doctors in California in order to receive more patient referrals and paid out more than $290 million in total. The labs have also been accused of fraudulent billing practices in civil suits filed in other parts of the country.

Takeaway: Quest Diagnostics and LabCorp continue to be named in whistleblower suits alleging fraudulent billing practices. G2

Quest Opens State-of-the-Art Megalab

Quest Diagnostics has unveiled a new, massive state-of-the-art laboratory in Massachusetts, which the company says will help modernize health care delivery.

The 200,000-square-foot facility is located in Marlborough, Mass., about 30 miles west of Boston. It will consolidate operations of about a half-dozen smaller labs Quest is operating in both Massachusetts and Connecticut. It will also host a research and development center for new lab tests. It is the first R&D facility for Quest in the region and the third companywide.

The lab is expected to be fully operational by the first half of 2015 and will employ 1,350 people in all, about 100 more than Quest had originally projected.

The lab dovetails with Quest's acquisition last year of the clinical outreach laboratory and anatomic pathology outreach laboratory business of the University of Massachussetts Memorial Medical Center. Quest said at the time of the deal it would consolidate the operations it had acquired into the Worcester facility, along with another lab it operates in Cambridge, Mass., as well as its Athena Diagnostics subsidiary. About a dozen physicians and faculty employed by UMass's medical group and school of medicine will provide scientific leadership for several facets of testing at the Marlborough lab.

"Our 'lab of the future' will set a new standard in diagnostic information services—not just for our company, but for our industry," said Steve Rusckowski, Quest's chief executive officer, in a statement. "It reflects a unique model for delivering innovative health services of the highest possible quality and value in order to create a healthier world."

Siemens Healthcare and Inpeco won contracts to automate the laboratory. The facility includes an automation track that is about 650 feet long that will be able to process several thousand blood samples per hour. The terms of the pacts were not disclosed.

A Quest spokesperson did not respond to a request seeking comment on the new laboratory.

Takeaway: Quest is expanding and consolidating its laboratory and research and development facilities on the eastern seaboard of the United States. G2

Mayo Clinic Sues Lab Executive Over Trade Secrets, Contract Breach

When Franklin Cockerill, M.D., announced his retirement as chief executive officer of the Mayo Clinic Medical Laboratories last July, he was apparently on the verge of tears. "Dr. Cockerill told his long-term colleagues he was retiring to help his aged mother with the family's fertilizer business in Nebraska," according to one account.

But the day after he left Mayo, Cockerill apparently started a job at rival Quest Diagnostics as vice president and chief laboratory officer.

That retelling of Cockerill's emotional retirement announcement came from a lawsuit Mayo filed in Minnesota state court last week, claiming that by seeking employment with Quest he breached his contract and misappropriated trade secrets.

"Dr. Cockerill's retirement plans included something entirely different than helping with his mother's business," claimed the suit, which said he had been planning his move to Quest for months before he left and had been involved in sensitive and high-level management meetings virtually to the final minute of his Mayo employment. The litigation also claimed that under Mayo's employment policies, seeking a similar job at Quest represented a conflict of interest.

The suit seeks an injunction against Cockerill, who had worked for Mayo since the 1980s, from disclosing trade secrets or other sensitive information to Quest. It also demands he repay Mayo his salary during the seven months he was allegedly planning to leave Quest. Based on Cockerill's 2012 compensation, that sum may be $350,000 or more.

It's the second lawsuit filed in the past month over a top-ranking lab executive leaving their job to go to a competitor. San Diego-based Millenium Health sued its nearby rival Pathhway Genomics in September over the recruitment of its former laboratory director.

In a statement released by his attorney last week, Cockerill said he was "disappointed that the Mayo Clinic has made such allegations and publicized its unproven claims in the media."

Takeaway: The recruitment of high-level laboratory executives by rivals may lead to protracted litigation. G2

Inside The Lab Industry

Labs Challenged in Creating Uniform Policies for Ebola Response

The first recorded cases of the Ebola virus in the United States have been unsettling sentinel events. The health care sector has appeared unsure in its ability to contain the handful of cases that have cropped up to date.

That's particularly the case with the two Dallas nurses at Texas Health Presbyterian Hospital who were infected by the virus as the result of treating Thomas Eric Duncan, a Liberian national who contracted the disease in Africa but did not become symptomatic until he arrived in the United States.

Both nurses contracted Ebola despite wearing protective gear and following protocols. Meanwhile, a Dallas Presbyterian lab employee took a pleasure cruise not long after her facility handled Ebola specimens. That has raised some questions about how prepared is the provider community—labs included—to confront the deadly virus.

> ***"At no time did Mr. Duncan's specimens leak or spill—either from their bag or their carrier—into the tube system."***
> ***—Texas Health Presbyterian Hospital***

Staff at Texas Health Presbyterian have also alleged that some of the most basic handling protocols were not followed, such as using hand-delivered specimens rather than the pneumatic tube delivery system.

"Regarding the ED tube delivery system utilized during Mr. Duncan's initial visit, all specimens were placed into closed specimens bags and placed inside a plastic carrier that travel[ed] through a pneumatic system," said Dallas Presbyterian in a statement that was issued on Oct. 16. "At no time did Mr. Duncan's specimens leak or spill—either from their bag or their carrier—into the tube system." The hospital added that the tube system was avoided completely when Duncan reappeared at the hospital after being sent home in late September. He was diagnosed with Ebola at that time.

In a webinar held earlier this month by the American Association for Clinical Chemistry (AACC), Sheldon M. Campbell, M.D., an associate professor of laboratory science at Yale University, observed that avoiding pneumatic tubes while handling Ebola specimens should be standard protocol.

Dallas Presbyterian appears to have paid a steep business price for having at least two of its health care workers infected, as well as the initial laxity involving its specimen handling. Its patient census dropped swiftly to 33 percent—an almost unheard-of number for a major urban facility and a stark state of affairs for a facility that accounts for about 17 percent of all revenue for its parent company, Texas Health Resources. Meanwhile, Moody's Investors Service has announced it has put Texas Health Resources on watch, suggesting it may make an announcement about its debt rating in the near term.

With the financial stability of providers treating Ebola victims potentially at risk, questions have arisen as to how labs will test for the presence of the virus, ensure their actions do not infect other employees, or even appropriately transport specimens if the need arises.

CDC Revises Guidelines

The federal Centers for Disease Control and Prevention (CDC), which initially appeared to suggest that the nurses who were infected had not completely followed protocol for wearing and shedding protective gear, instead revised its protective guidelines earlier this month for health care workers and handling laboratory specimens.

It was recommended that front-line health care workers exposed directly to patients wear a hood-style mask that drapes to the shoulders, and special coverings on their feet.

As for laboratory workers, the CDC recommended that "any person testing specimens from a patient with a suspected case of Ebola virus . . . should wear gloves, water-resistant gowns, full face shield or goggles, and masks to cover all of [the] nose and mouth." The agency also recommended as an additional precaution the use of a certified class II biosafety cabinet or Plexiglas splash guard.

"U.S. clinical laboratories can safely handle specimens from these potential Ebola patients by taking all required precautions and practices in the laboratory, specifically designed for pathogens spread in the blood," the CDC said in its interim guidance.

Nancy E. Cornish, M.D., a medical officer with the division of laboratory science and standards at the CDC, said during the AACC webinar that labs should consider elevating their biosafety levels and work at least at biosafety level 4 if the facility believes it may have to handle suspected Ebola cases.

Meanwhile, transporting of suspected Ebola specimens has become far more complicated. Campbell suggested that labs in Connecticut would encounter difficulties transporting Ebola specimens for testing. Although he deferred to state health authorities when asked for more specifics, policies elsewhere suggest he's correct.

Quest Diagnostics, the nation's largest laboratory, told at least one news outlet this month that it will not undertake blood draws or handle specimens from suspected Ebola patients. A Quest spokesperson did not respond to a request for comment.

"Any person testing specimens from a patient with a suspected case of Ebola virus . . . should wear gloves, water-resistant gowns, full face shield or goggles, and masks to cover all of [the] nose and mouth."
—Centers for Disease Control and Prevention

In Canada earlier this week, Air Canada refused to transport a specimen for a suspected Ebola case from Edmonton to Winnipeg, causing a delay in testing.

The Emory University Hospital in Atlanta, which has treated some American relief workers who were transported back from Africa after being stricken by the disease, decided against transporting any specimens at all except to the nearby CDC, relying instead on point-of-care (POC) testing at patient isolation sites.

"We believe . . . that this policy was highly effective and beneficial in alleviating any initial concerns about potential exposure among phleboto-

mists and laboratory personnel. Nevertheless, it created the need for us to offer a broader range of POC tests within the unit that might be required for optimal care of patients infected with Ebola," wrote pathology department physicians and personnel in a recent issue of the journal *Laboratory Medicine*.

The UCLA health care system, which operates two hospitals in the Los Angeles area, recently announced that all Ebola-related testing would be performed at a special mobile laboratory in order to minimize any risk of spreading the virus.

The California Department of Public Health (CDPH) is in the middle of negotiating with several hospitals that would be designated to care for any Ebola patients in that state. However, there are only 13 labs nationwide that are certified to confirm Ebola cases, with California's sole facility in Los Angeles. The lab has helped to rule out two suspected cases so far, in the Los Angeles and Sacramento areas—350 miles away from one another.

"We've had a plan in place for the past six weeks, and we're continuing to try and improve and modify it."
—Curt Hanson, M.D., pathologist and lab scientist, Mayo Clinic

At a recent media briefing, CDPH Director Ron Chapman, M.D., said that his agency had already contracted with a courier service certified by both state and federal authorities to transport suspected Ebola specimens. That company, World Courier, is a subsidiary of AmeriSource Bergen. It transported the suspected Ebola specimen in Canada that had encountered delays.

Meantime, the CDC recommended in its interim guidelines that "risk assessments should be conducted by each laboratory director, biosafety officer, or other responsible person to determine the potential for sprays, splashes, or aerosol generated during laboratory procedures."

UCLA tested its mobile lab during a recent safety drill, and the Mayo Clinic is engaged in drills that involve not only laboratory staff but virtually any employee who might be involved in or would be near a specimen.

"We've had a plan in place for the past six weeks," said Curt Hanson, M.D., a Mayo Clinic pathologist and lab scientist, "and we're continuing to try and improve and modify it."

Hanson noted that one of the keys to maintaining integrity of the handling process is to communicate to everyone on every level what their role is and how it should be carried out. Practices, or "dry runs," as he calls them, have also been carried out. Those are crucial to determining if there have been any breaches in protocol. When they're discovered, staff is educated further.

"Anytime you put in an institutionwide process in an enterprise as big as a hospital, there can be complications, poor planning and communication," Hanson said. "But the practice is crucial, and in the laboratory, it teaches us how to do things with less movement, less people, and less exposure."

Takeaway: The outbreak of the Ebola virus has put laboratories on their toes and has made contingency preparations virtually mandatory to ensure testing is performed in an appropriate and timely manner. G2

■ PAML, Cleveland Clinic Labs to Share High-End Tests, *from page 1*

Cleveland Clinic," he said, adding that the arrangement will fill some gaps in the menus of both labs for complex tests.

Cleveland Clinic officials did not immediately respond to a request seeking comment.

Both labs have sophisticated transportation networks—PAML has clients as far east as New Jersey—so the test-sharing collaboration is not expected to incur additional costs. Velázquez also noted that the turnaround times already in place for these assays would be unchanged.

"Mainly, we had to work together, develop some logistics and infrastructure, but there was minimal incremental cost," he said. Velázquez did not disclose what the annual shared test volume would be under the collaboration.

Velázquez added that the next step in the collaboration—test development—would commence within the next six months. The two labs had announced last year they had entered into a strategic alliance, but few details had been released until now.

Susan Steagall, a laboratory industry consultant in Salem, Ohio, suggested the collaboration is fairly unique. Most such partnerships, she observed, have come between academic laboratories or those with large stakes in managed care, such as Kaiser Permanente or the Geisinger Health system.

Heather Creran, an Atlanta-based laboratory business consultant, believes that providers are compelled these days to seek unusual alliances.

"It is not surprising that two leaders in the evolution of health care such as Cleveland Clinic and PAML are collaborating," she said. "In order to survive, traditional health care companies will quickly need to figure out how best to deliver health care more efficiently, conveniently, and at a lower cost. It will be imperative for health care providers to partner, even with entities that they may have considered competitors in the past."

And given the current laboratory business environment, "I can see where [such alliances] could become a trend," Steagall observed.

Velázquez said the collaboration came as a result of PAML's reaching out to a variety of large laboratories to seek an alliance. He noted that the Cleveland Clinic's lab was the only one whose management was interested in working together without a focus specifically on the bottom line.

"I was somewhat disappointed that our other colleagues in the industry did not do this for something greater than ourselves," he said. "It's not 'What we are going to do for me, and how much should we charge you?' but how can we develop a better model [for care]."

Regarding test development, for example, working together would eliminate duplicative costs for research and allow both labs to offer the tests down the line. Velázquez said he did not believe that new facilities would need to be constructed for this stage of the collaboration.

Takeaway: The collaboration between PAML and the Cleveland Clinic Laboratories has been positioned as less of a business arrangement and more as a path toward improving both laboratory operations and clinical care. G2

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INDUSTRY BUZZ

Sequenom Obtains Prenatal Testing Rights From Development Partner

Sequenom, the San Diego-based genomic laboratory, has purchased intellectual property rights from Oxford University regarding certain aspects of noninvasive prenatal testing.

Sequenom paid $14.6 million to Isis Innovation Limited, an Oxford-affiliated development company, for the rights to the information. That sum includes $3.2 million as a final royalty payment under a prior agreement between the two companies. Sequenom also agreed to waive $2.1 million in legal fees Isis was previously obligated to pay.

The property includes a portfolio of patents in the United States, Europe, Japan, Hong Kong, Canada, and Australia. Sequenom said they cover noninvasive prenatal genetic diagnostic testing on paternally inherited fetal nucleic acids derived from maternal plasma or serum. The technology is part of the firm's MateriT21 PLUS diagnostic test. Sequenom previously had exclusive rights to the property as part of a licensing agreement it had entered into with Isis Innovation in 2005 but did not own them outright.

"The patents purchased from Isis Innovation will enable us to strengthen our intellectual property position worldwide, while reducing future expenditures," said William Welch, Sequenom's chief executive officer. "We look forward to leveraging this important intellectual property for additional applications of our technology in the future."

However, the U.S. version of the patent is currently under dispute, stemming from a legal battle involving Sequenom and San Jose, Calif.-based Ariosa Diagnostics. Ariosa sued Sequenom in 2011 to obtain a declaratory judgment that its own Harmony prenatal test did not infringe on Sequenom's patent.

A U.S. District Court in Northern California ruled last year that certain claims of the patent cannot be held by Sequenom and decided in favor of Ariosa. That judgment is currently under appeal, and Sequenom also received favorable judgments on seven claims of its patent from the U.S. Patent Trial and Appeal Board. The patent is not in dispute on other continents.

In addition to those payments and waivers, Sequenom may also make future payments to Isis if revenues derived from the intellectual properties exceed certain thresholds.

Takeaway: Sequenom is moving forward in locking up all the rights to the technology underlying its primary prenatal laboratory test.

References

Centers for Disease Control and Prevention
800-232-4636

Cleveland Clinic Laboratories
216-444-5777

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LabCorp
336-584-5171

Mayo Medical Laboratories
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