Your Independent Source for Business & Financial News

LABORATORY INDUSTRY REPORT™

Vol. 14, Iss. 2, January 16, 2014

HIGHLIGHTS

www.G2Intelligence.com

University of Colorado Develops Comprehensive New Drug Assay

The University of Colorado School of Medicine has developed a sweeping new toxicology panel it claims will detect the presence of drugs at a much lower levels and with significantly less labor than existing assays.

If true, the test could potentially be a game-changer in the highly competitive drug testing segment, which has seen significant growth among laboratories in recent years. Several enterprises that focus specifically on drug testing have become labs with extensive regional or even a national presence.

According to university officials, the test can detect more than 500 different drugs in 19 separate categories via a single urine sample undergoing mass spectrometry and molecular analysis. Secondary testing to provide accurate data, or to focus on the detection of specific drugs, is unnecessary.

Continued on page 7

Quest, UCSF Enter Pact to Develop Esoteric Tests

In what appears to be a move to jump-start its bottom line over the long term, Quest Diagnostics has entered into a pact with the University of California, San Francisco (UCSF) to develop precision—and presumably profitable—esoteric tests.

The deal formalizes what had been a casual relationship between the New Jersey-based Quest and UCSF, which is one of the premier medical research facilities in the United States.

"This unique collaboration between UCSF and Quest brings together the finest researchers and clinicians in the country to accelerate the development of a 'product pipeline' of scientific discoveries as clinically valuable diagnostic solutions that enable precision medicine for improved outcomes," said Jay Wohlgemuth, M.D., a Quest senior vice president who oversees its science and innovation division.

Under the terms of the deal, Quest will pay UCSF grants of $100,000 to $500,000 for each specific project, as well as cover expenses related to research and development and population testing.

Continued on page 2

■ **Quest, UCSF Enter Pact to Develop Esoteric Tests,** *from page 1*

Quest will market and distribute any laboratory-developed tests that arise from the project. There may also be provisions for royalty payments and licensing fees to UCSF, although specifics were not immediately available.

The deal is the first of its kind that UCSF's innovation arm has signed with a laboratory.

Quest and UCSF will embark immediately on developing tests focused on two areas that have lacked specific assays: the quicker diagnosis of autism and targeting more specific treatments for forms of pediatric brain tumors. Other collaborations are also expected in the near term, officials said.

Both parties have collaboratively conducted autism research in the past but to date have not made an enormous amount of headway.

"While a few gene mutations have been identified in autism, even the most common of those is only represented in 1 percent of children with the disorder. That makes it very difficult for a single research institution to make any real progress in identifying the connections between those genes and clinical symptoms," said Kristen Bole, a UCSF spokesperson.

> ***"This puts Quest more into the 'r' camp rather than the 'd' camp."***
> ***—Amanda Murphy, Analyst, William Blair & Co.***

For the development, researchers will rely on Quest's Health Trends database. It contains the records of 1.5 billion patient encounters involving lab tests and adds another 500,000 results every year.

"With UCSF, we expect to analyze this data to identify potential biomarkers and, based on findings, potentially develop new tests," said Quest spokesperson Wendy Bost. "The size of the database makes it highly useful for performing meaningful population studies, particularly on small patient populations" such as the subset being studied for autism-related assays.

Should Quest and UCSF enjoy success in developing these tests, their esoteric nature means they likely could be marketed at price points in the high three figures or even well into the four figures—the type of test that could prove a boost to Quest's bottom line if annual sales prove significant.

Despite being the nation's largest laboratory company, Quest has been struggling with growth as of late. Its revenues have trended flat for the past few years and are actually expected to drop 3.5 percent for calendar year 2013, according to its recently issued financial guidance.

"This puts Quest more into the 'r' camp rather than the 'd' camp," said Amanda Murphy, an analyst with the investment banking firm William Blair & Co. She believes it might signal a change in Quest's strategy to try to build a more robust test menu for the long term.

"It's always about keeping the test menu relevant," she said—along with fighting off reimbursement cuts that have been eroding revenues.

Quest officials demurred from directly saying the UCSF pact this was part of a long-term business strategy but did not deny it, either.

"We are committed to delivering innovations that will improve patient care and health while also creating differentiated value and growth for Quest. Collaboration is a key pillar of our innovation strategy," Bost said. "We believe our relationship with UCSF, a top academic leader in translational research and precision medicine, will, over time, generate clinically important medical innovations that advance clinical management for patients and business growth for Quest."

Takeaway: Quest's strategy may be shifting to develop more lucrative tests in a long-term plan to build revenue and profits.

Insight Genetics Receives National Cancer Institute Grant

Insight Genetics (Nashville, Tenn.) has received a $1.5 million grant from the National Cancer Institute (NCI) to continue the development of a test intended to better direct therapies at patients with non-small cell lung cancer.

The grant was made as part of NCI's companion diagnostics development program. It will be used for Insight to continue development of its ALK Resistance assay. The test, which was developed by St. Jude Children's Research, detects all mutations promoting treatment resistance in anaplastic lymphoma kinase, one of the genetic drivers of non-small cell lung cancer. It is offered through the Insight Molecular Lab division, primarily to assist in the selection of patients for clinical trials involving ALK inhibitors.

Although such cancers may initially respond to forms of treatment that inhibit ALK, ongoing mutations mean that such medications are usually rendered therapeutically useless within a year. That prompts oncologists to look for other medications to treat the patient, but diagnostics are often required to determine which regimen would work the best.

"Resistance is a growing concern in the cancer treatment world," said Eric Dalhauser, Insight's chief executive officer. "The Insight ALK Resistance assay meets a significant unmet need in . . . lung cancer by giving physicians a way to monitor their patients for drug resistance and providing information to help them determine the most effective course of treatment."

According to company officials, the test requires minimal biopsied material and has a turnaround time of 48 hours.

The grant is the sixth to Insight from NCI. The company said it would use the funds to further the test toward a premarket approval application with the U.S. Food and Drug Administration.

Takeaway: The National Cancer Institute is continuing to invest millions of dollars to develop companion diagnostics to further refine and improve oncology care.

Pathologists Decry New Cuts to Cytology, Immunohistology

Call it 88305, the sequel. That is the prevailing sentiment among pathologists regarding reimbursement cuts that focus on cytology and immunohistology procedures recently implemented by the Centers for Medicare and Medicaid Services (CMS).

The biggest cuts involve cytopathology cell enhancement, CPT code 88112. The global payment was reduced 43 percent, from $109.55 to $62.73, according to data from the College of American Pathologists. That included a 52 percent reduction in the professional component payment and a 33 percent cut in the technical component payment.

Joanathan L. Myles, M.D., a Cleveland Clinic pathologists who chairs CAP's economic affairs committee, believes the cuts will create an overall 6 percent reduction in revenues for pathologists.

"Clearly for independent laboratories, the economic reality of this is going to be pretty rotten."
—Barry Portugal, president, Health Care Development Services

However, cytology procedures usually do not make up a large proportion of any specific practice, according to Robert DeCresce, M.D., president of University Pathologists, an 18-physician practice in Chicago. But specialty practices that focus on flow cytometry, GI pathology, dermopathology, and uropathology might take a comparatively larger hit, he added.

CMS also eliminated the professional and technical components of immunohistology-related antibody slide staining, CPT code 88342, replacing them with a series of G-codes. Several clinicians say the change not only deeply reduces reimbursement for multiple staining but actually penalizes them for undertaking the deep analysis crucial for detecting cancers and other serious medical conditions.

The global payment under the old code was $115.34. It's now $88.04, a cut of more than 23 percent. The global payment for a subsequent stain had been the same rate. It was cut to $68.08, including a payment of only $12.48 for the professional component. The prior professional component payment was $42.19.

The reductions take place just a year after a 52 percent cut in reimbursement for the technical component of CPT code 88305, a bread-and-butter procedure for pathologists that many say has gouged deeply into the cash flow of their practices. Pee Dee Pathology Associates, an eight-doctor practice in Florence, S.C., for example, took a 10 percent hit in revenues, with no offset in overhead. Similar revenue losses were reported by other practices.

"Clearly for independent laboratories, the economic reality of this is going to be pretty rotten," said Barry Portugal, president of Health Care Development Services, a consulting firm in Nokomis, Fla.

Portugal added that the changes will also hit hospital labs that employ pathologists as independent contractors, particularly regarding the technical component of pricey procedures such as a 12-core prostate biopsy. Such

a procedure costs Medicare about $840 for both the technical and professional components in the past. Now, it will be less than half of that amount altogether, according to Portugal.

Economic Hit Not Yet Fully Analyzed

Most the pathologists interviewed by *Laboratory Industry Report* have yet to fully analyze the financial impact the cuts will have on their practices. For the most part, their books of business from Medicare range from about 30 percent to 40 percent.

However, CellNetix Pathology & Laboratories, a sizable Seattle-based practice, calculates the code changes will cost it $600,000 a year. It is "quite a significant hit," said Donald Howard, M.D., CellNetix's chairman and chief executive officer.

According to DeCresce, CMS paid for each slide stain at an equal rate. Now, payment is on sliding scale that is reduced with subsequent stains.

"They're smashing the payments down because Quest and LabCorp can do it at those rates, and they're looking to save money."
—Kenneth Ries, M.D., chief executive officer, Pee Dee Pathology Associates

"The old code paid $42 per stain. When I used to do two stains, I would get $84. Now I am getting $54. For four stains, I used to get $168. Now I am getting $68," he said. For a lymphoma analysis, which requires nine or 10 stains, the cuts are geometrically deeper, he added.

Another pathologist, Stephen Ruby, M.D., medical director of 4path Ltd. Pathology Services, a three-physician practice in Justice, Ill., likened the change to the G-codes to a student being instructed to color in a clown with three different crayons—but prohibited from using more than one color in a drawing. The end result is three pictures of incompletely drawn clowns.

"What [the government] is saying is that you have to buy all these crayons. And we'll pay you a dollar for the first crayon you buy to color in that picture, and 60 cents for the next," Ruby said. "But I am not paying less for the antibodies just because they are the second or third antibody used in a case." As a matter of fact, reagent costs went up 7 percent over the last year for Ruby's practice.

Not only are fixed expenses still in place, but Ruby noted that pathologists will get paid significantly less for the complicated multilayered stains used to analyze breast lesions and prostate biopsies to make cancer diagnoses.

Myles also noted that the shift to the G-codes could also be emulated by private payers, and that pathology practices would have to check their contracts to see if those changes will be implemented.

Kenneth Ries, M.D., Pee Dee's chief executive officer, described the methodology CMS adopted as a "sledgehammer" approach.

"They're smashing the payments down because Quest and LabCorp can do it at those rates, and they're looking to save money," he said—without taking into account the fact that smaller practices do not have the economies of scale enjoyed by the national players.

Tough Choices Remain

The latest round of reimbursement cuts will prompt the pathology practices to further scrutinize their expenses and determine what other costs they may be able wring out in the near term.

Pee Dee, for example, has decided not only against hiring any new pathologists, but it will likely not fill positions as they become vacant. Two of its doctors—fully one-quarter of its practice—are nearing retirement and will likely not be replaced.

> ***"I no longer have the ability to reinvest in the practice."***
>
> ***—Stephen Ruby, M.D., medical director, 4path Ltd. Pathology Services***

"We'll see how it goes with seven pathologists when one leaves. We may even see how things do with a staff of six," Ries said.

Ruby has not been able to provide any raises for his staff of 15 since the cuts back in January 2013, and that does not take into account the current cuts. He has initiated renegotiations with his reagent suppliers to try to peel back some of the recent price increases.

"I no longer have the ability to reinvest in the practice," he said.

More concerning among the pathologists is how care may be impacted by the ongoing reductions, which include not only this round of cuts but the 88305 cut, the sequester, and other reimbursement changes.

"It is really a shame because ultimately, we will either no longer do the work for these particular payers, and there will be a decline in the level of service, or you will just have the risk for less complete levels of study, because certain tests will be no longer cost-effective [to perform]," Ries said.

None of the pathologists thought that the rollout of the Affordable Care Act would help their bottom lines in significant ways. Ruby, for example, expressed concerns that those enrolled in commercial plans via the state exchanges might balk at making deductible and copayments on their coverage when they receive bills. And while millions of other Americans will also be enrolled via an expansion of Medicaid, the rates paid under that program are meager compared to Medicare.

"What it's done, it really puts labs at risk of not being able to survive, period," Ruby said. "And if we can't survive, there is a whole segment of the population who will lose a large part of their medical services and medical resources."

Takeaway: The recent cuts in cytology and immunohistology reimbursements compound last year's 88305 cuts, putting the survival of some pathology practices in question. G2

University of Colorado Develops Comprehensive New Drug Assay, *from page 1*

The test can also detect drugs such as codeine at levels of 10 nanograms per deciliter, compared to many other assays, which cut off detection at 300 nanograms per decileter. As a result, officials claim the new assay will detect five times the level of drug use than other tests on the market. In one comparison test, the assay detected twice as many positives for cocaine, and three times as many positives for codeine, compared to other screening techniques.

The test was developed by the university about four years ago as a research project, with clinical sample assays beginning in late 2011. About 10,000 test assays were performed to confirm accuracy, officials said, and there have been no known false positives.

Although data from Quest Diagnostics, the nation's largest laboratory, indicate that positive drug tests have been on the decline in recent years, positives for prescription painkillers have been on the rise. Data from the Centers for Disease Control and Prevention also indicate deaths from that category of drugs have surpassed overdose deaths from illicit narcotics. And positives for multiple drugs in a single test occur up to 11 percent of the time, according to data from Ameritox.

"Polypharmacy, or the use of multiple drugs at once, is the newest American epidemic; more than one in five U.S. citizens are using three or more prescription drugs, and more than one in 10 are using five or more," said Jeffrey Galinkin, M.D., a professor of anesthesiology and pediatrics at the University of Colorado School of Medicine. "Combine that with the fact that drug overdose death rates in the U.S. have more than tripled since 1990, and it's clear the industry is in crisis and desperately needs a more comprehensive urine drug test."

The university appears assured of the test's success: It launched a not-for-profit company, CU Toxicology, to distribute the test, with Galinkin serving as its chief medical officer. It already has 25 employees and two dozen clients in Colorado, Pennsylvania, and Michigan, including Kaiser Permanente's Colorado division. Testing takes place at an 8,000 square-foot lab on the School of Medicine campus in Aurora, Colo.

The test retails for between $100 and $200 depending on how results are structured, according to Blair Whitaker, CU Toxicology's director of business operations. Turnaround times are between 24 and 48 hours depending on what time of the workday a sample is received. Test data is provided electronically. Samples must be mailed in by clients; there is no courier or outreach service.

Current test volume is relatively low, at about 2,000 assays per month. But Whitaker projects it will more than double, to 5,000 a month, by the end of the year.

"We believe in the area of drug abuse, and the discovery of abuse, we have a very novel technology," Whitaker said.

Takeaway: A new drug test developed by the University of Colorado could raise the bar for sensitivity of testing—as well as market competition.

A Bloomberg BNA Business
INDUSTRY BUZZ

Quest Enters Sequencing Deals to Expedite New Test Development

Quest Diagnostics has entered into agreements with two California-based biotech companies to expand the use of their gene sequencing platforms in order to develop new molecular assays.

Quest reached a multiyear deal with Life Technologies Corp. to use its Ion Torrent platform and expanded an existing agreement it reached last year with Illumina Inc. to use its MiSeq platform.

Under the terms of the new agreement with Illumina, Quest expanded its rights to use MiSeq and will apply it in diagnostic assays involving cancers, neurology disorders, and women's health. Quest also reserved the right to use the platform for biomarker detection in clinical trials performed for pharmacy, biotech, and other outside clients. Under the deal with Life Technologies, its platform will be used to develop assays in more than a dozen areas of medicine.

"Investing in next-generation sequencing [NGS], which is increasingly used in several clinical areas as well as clinical trials, is a key element of our strategy. Illumina is a leader in NGS innovation, and this new broad agreement will give us a greater level of flexibility to build on our record of success in NGS to include several diseases where sequencing-based molecular testing can meaningfully improve clinical care," said Jay Wohlgemuth, M.D., a Quest senior vice president.

Financial terms of the agreements were not disclosed.

According to Zacks Research, the deals will be used to help Quest consolidate leadership in the esoteric market. "Quest Diagnostics will be in a position to develop innovative molecular tests and deliver results speedily and accurately. Management expects to gain momentum by focusing on diverse fields of treatment," Zacks said in a recent report.

Both the Ion Torrent and MiSeq platforms fit on a desktop and have been positioned as high-speed, low-cost products. They have generated considerable demand because of their ability to perform the kind of genetic sequencing required to develop molecular assays.

Takeaway: Quest Diagnostics is willing to invest in extensive deals with biotech firms in order to ensure it has considerable resources in next-generation sequencing to be able to develop new assays.

References

- 4path Pathology 877-884-7284
- CellNetix Pathology & Laboratories 866-236-8296
- College of American Pathologists 800-323-4040
- CU Toxicology 303-724 7346
- Health Care Development Services 847-498-1122
- Pee Dee Pathology Associates 843-664-4300
- Quest Diagnostics 800-222-0446
- UC San Francisco 415-476-9000
- University Pathologists 312-942-8850
- William Blair & Co. 312-236-1600

Note our change of address and phone numbers effective immediately.
To subscribe or renew *LIR*, call now +1-603-357-8101, 800-531-1026
(AAB and NILA members qualify for a special discount, Offer code: LIRNI1)

Online: www.G2Intelligence.com/LIR
Email: customerservice@G2Intelligence.com
Mail to: G2 Intelligence
24 Railroad Street
Keene, NH 03431-3744 USA
Fax: +1-603-357-8111

Multi-User/Multi-Location Pricing?
Please email jping@G2Intelligence.com or call 603-357-8160.