G2 INTELLIGENCE
A DIVISION OF PLAIN LANGUAGE MEDIA

Your Independent Source for Business & Financial News

LABORATORY INDUSTRY REPORT™

Vol. 15, Iss. 17, September 17, 2015

HIGHLIGHTS

TOP OF THE NEWS

CMTP Issues Draft Framework for Covering NGS Testing 1

NeoGenomics Enters Into Hospital Testing Deal With Premier 1

Exosome Raises Second Round Funding, Close to Launching Cancer Tests 2

Health Diagnostic Laboratory Sold at Auction 3

INSIDE THE LAB INDUSTRY

Point-of-Care Tests Likely to Become Bigger Factor in Lab Business Moving Forward 4

INDUSTRY BUZZ

NantOmics Acquires OncoPlex Diagnostics 8

www.G2Intelligence.com

CMTP Issues Draft Framework for Covering NGS Testing

An influential not-for-profit group has issued a draft framework for how next-generation sequencing tests for oncology care should be reimbursed by payers.

The report from The Center for Medical Technology (CMPT) comes at a time when anxiety regarding the rates of reimbursement for molecular-based tests has been running high. Many of the regional fiscal intermediaries for Medicare have lagged in providing guidance on payment, prompting many commercial insurers to not cover many tests themselves, or offer payments at rates far lower than what the laboratories consider reasonable. And intermediary Palmetto GBA's efforts to create standardized codes for such tests through its MolDX system have also caused the laboratory sector additional anxiety. Meanwhile, many labs have been releasing and touting tests and platforms that rely on next-generation sequencing.

Continued on page 7

NeoGenomics Enters Into Hospital Testing Deal With Premier

In a bold move intended to expand its hospital business, the Florida-based molecular laboratory NeoGenomics has entered into a three-year agreement with Premier, the health care sector's predominant group purchasing organization (GPO).

The agreement covers all of NeoGenomic's oncology testing services, including its next-generation NeoTYPE cancer profiles. The services will be made available to some 3,600 hospitals that participate in the Premier network—about 80 percent of all of the acute care facilities in the U.S. The NeoTYPE product can assess tumor profiles and gene drivers for 17 different types of solid tumor cancers, including brain, gastric, lung, pancreatic, and head and neck cancers. It can also profile eight different hematologic cancers, including lymphoma and myeloma.

A GPO typically acts as a purchaser of supplies and medical equipment for hospitals. It does not usually work closely with many laboratories.

Continued on page 2

NeoGenomics Enters Into Hospital Testing Deal With Premier, *from page 1*

"There are not a lot of GPO deals with labs," acknowledged Steve Jones, executive vice president of finance for NeoGenomics. "There are a lot of regulatory hurdles, and structuring this took a lot of time and attention."

> *"NeoGenomics did a masterful job of selling their innovative and trademarked NeoTYPE cancer profiles to Premier."*
>
> — Peter Francis, President, Clinical Laboratory Sales Training

Peter Francis, president of Clinical Laboratory Sales Training in Maryland, noted that GPO agreements are fairly common for reference laboratories, and they do confer some notable advantages. "It gives the laboratory significant leverage when selling their services to any member," he said.

The deal will position NeoGenomics as an in-network laboratory provider for Premier, a first for a lab specializing in oncology. It represents a big opportunity for NeoGenomics to get in front of the large bulk of the hospitals in the U.S. without having to rely heavily on its sales force. Jones noted that nearly half of its revenue is currently derived from hospital sales, compared to slightly more than a quarter from commercial payer contracts. Francis described the deal as "groundbreaking" because so few of the GPO/lab contracts focus on specialty services. "Frankly, it's somewhat refreshing to see a GPO amplify its in-network vendor list to include a niche reference laboratory," he said, adding that "NeoGenomics did a masterful job of selling their innovative and trademarked NeoTYPE cancer profiles to Premier."

According to Jones, NeoGenomics will bill the hospitals directly for services rendered and will actually contract with them directly in order to comply with federal regulations. Premier will receive 3 percent of the agreed-to payment under a specially structured safe harbor provision. No hospital that contracts with Premier will be required to purchase service from NeoGenomics, he added.

NeoGenomics has not provided any estimates on test volume or sales that could be derived from the deal, although Jones did expect it would boost the company's numbers in the long-term. "It is helpful to get a good housekeeping seal of approval like this," he said. Shareholders were heartened by the deal, which was announced in early September. Shares in NeoGenomics traded up about 10 percent the day the deal was announced, reaching about $6.50 per share, and they have remained there since.

Takeaway: NeoGenomics is using a twist on group purchasing practices to expand its business dealings with hospitals. G2

Exosome Raises Second Round Funding, Close to Launching Cancer Tests

Exosome Diagnostics has continued on its capital raising roll, bringing in another $17.6 million in financing, and its series B total to $44.7 million.

The latest round was funded by Forbion Capital Partners, NGN Capital, Arcus Ventures, Tiger Management and CD Ventures. The company said it would use the money to launch later this year three "liquid biopsy" molecular tests, two for lung cancer and one for prostate cancer. The lung cancer tests would focus on the detection of the ALK and T790M mutations and help focus on the appropriate targeted therapies for care. The prostate test will determine if patients are suffering from the "high-grade,"

or more aggressive, form of cancer. It will also launch a solid tumor panel that will focus on identifying 26 specific genes in colon, breast and lung cancers. Exosome expects to launch a next generation sequencing platform in 2016 and another molecular test for neurodegenerative conditions.

"It well positions us to successfully transition to a commercial-stage company that will deliver breakthrough cancer diagnostics to dramatically enhance physicians' ability to make informed treatment decisions based on comprehensive, real-time molecular insights," said Thomas McLain, chief executive officer of Exosome Diagnostics, in a statement. The company opened a CLIA-certified laboratory in mid-August. In January, it entered into a collaboration with the California-based Bonnie J. Addario Lung Cancer Foundation to speed up the development of blood-based lung cancer tests.

Recent data from Exosome's ExoDx liquid biopsy test for the ALK gene indicated a 88 percent sensitivity rate and a 100 percent specificity rate. Its assay for solid tumors indicated a 72.7 percent concordance rate for EGFR mutations.

Takeaway: Exosome Diagnostics is gearing up both financial and technologically to roll out a variety of molecular diagnostic tests. G2

Health Diagnostic Laboratory Sold at Auction

Health Diagnostic Laboratory (HDL) has been acquired in a bankruptcy auction earlier this month for a fraction of its value of just a couple of years ago. Virtually all of the assets of the Richmond, Va.-based HDL were acquired by Frisco, Texas-based True Health Diagnostics for $37.1 million. The sale is still subject to the approval of a U.S. Bankruptcy Court judge.

HDL's test volume during the first quarter of 2015 was about half of what it had been in 2013.

"The auction was robust and competitive, and we believe our objective of maximizing the value of the assets of HDL to best serve the interests of our creditors and other stakeholders has been achieved," said HDL Executive Vice President and General Counsel Douglas Sbertoli in a statement. HDL filed for bankruptcy protection last June after it was unable to pay its creditors in an orderly fashion. Its 2013 revenue of $375 million was 10 times its recent sales price.

HDL had been battered by a federal investigation into its practice of reimbursing physicians for handling and shipping of lab specimens. In June 2014, the U.S. Department of Health and Human Services' Office of the Inspector General issued a fraud warning regarding the payments by laboratories to physicians to process samples, warning those payments could constitute an illegal kickback. The company's business practices were detailed by the *Wall Street Journal* in a front-page story about three months later, prompting the resignation of company co-founder and CEO Tonya Mallory not long after. HDL's test volume during the first quarter of 2015 was about half of what it had been in 2013. Mallory was recently sued by the U.S. government, which has accused her of engaging in a kickback scheme that prompted it to pay hundreds of millions of dollars for unnecessary tests.

Takeaway: The once high-flying Health Diagnostic Laboratory is no longer an independent entity. G2

Inside The Lab Industry

Point-of-Care Tests Likely to Become Bigger Factor in Lab Business Moving Forward

For decades, the mechanics of laboratory testing have been at a physical remove from the bulk of health care delivery. A blood draw or tissue sample is performed on a patient at one site and the material is transmitted to a lab for testing. The results are then sent back to the original site or yet another locale.

"[T]he success of a potential shift from curative medicine, to predictive, personalized, and preemptive medicine could rely on the development of portable diagnostic and monitoring devices for point-of-care testing."

— National Institutes of Health

That model is likely to remain in place for decades to come. But the laboratory business is also likely to see a significant portion of the tests it performs shift to point-of-care (POC) testing.

Although POC testing has been around for decades itself, such assays require regulatory approval from the U.S. Food and Drug Administration, which is usually much more stringent than Clinical Laboratory Improvement Amendments. The bulkiness of POC test hardware has also made them a limited option for clinicians, who have mostly used them to perform very basic assays. Initially, POC tests were developed for glucose and blood gases in the 1980s. But even with significant advances in technology in the decades since, there are only about 100 POC tests currently available on the market, out of the thousands a typical laboratory can conduct.

Change in Market Forces

But a variety of factors have come into play in recent years that make POC testing a more desirable option. They include the proliferation of retail clinics at big box pharmacies—which makes performing such tests a more urgent matter—advances in technology, and the need for convenience. And while many POC tests are more expensive than assays performed in a large lab, they can still reduce the overall cost of rendering care by getting a patient treatment much sooner than waiting a day or two for test data.

According to a recent report by the National Institutes of Health, "the success of a potential shift from curative medicine, to predictive, personalized, and preemptive medicine could rely on the development of portable diagnostic and monitoring devices for point-of-care testing."

As a result, there has been a demand for laboratory testing to become more mobile, whether through POC assays or other means. This may be best illustrated by the recent launch of DispatchHealth, a Denver-based enterprise that provides mobile healthcare services. Each of the vehicles it uses includes a CLIA-certified laboratory, apparently among the first-ever mobile labs to ever receive such certification.

Inside The Lab Industry

"Consumers now have a new option to address individual health care needs without the expense, inconvenience and time requirements often associated with urgent and emergency care facilities," said DispatchHealth Chief Executive Officer Mark Prather, M.D., in a statement. He declined to be interviewed for this article.

The UCLA-developed device can scan the ELISA slide in the field and wirelessly send data back to a computer server.

The retail clinic surge has also led to changes regarding how pharmacists are being trained. Roosevelt University's College of Pharmacy in Chicago, one of the bigger pharmacy schools in the Midwest, has begun training and certifying its students to administer POC tests for maladies such as strep throat and influenza. With a certification in place, they can prescribe antibiotics or antiviral medications after a positive test without a physician's prescription.

"I expect POC testing to become an even bigger phenomenon than all of the immunizing that is being done by pharmacists at community pharmacies all across the nation," said Roosevelt College of Pharmacy Dean George MacKinnon in a statement.

Meanwhile, technological advances are making many POC tests—which even in smaller incarnations still often require a platform ranging in size from a desktop printer to a toaster—accessible from a smartphone. Researchers at the University of California at Los Angeles have developed an enzyme-linked immunosorbent assay (ELISA) platform that can be run through a smartphone with a special attachment that is produced by a 3-D printer. Traditional ELISA platforms are used to test for diseases such as HIV, West Nile virus, hepatitis B, mumps, measles, and herpes simplex.

The UCLA-developed device can scan the ELISA slide in the field and wirelessly send data back to a computer server. Test results are then transmitted back to the smartphone within 60 seconds. Field testing indicated the smartphone platform was 99.6 percent accurate in diagnosing mumps, 99.4 percent accurate diagnosing herpes, and 98.6 percent accurate diagnosing measles.

Johns Hopkins University has also developed a nucleic acid amplification testing (NAAT) chlamydia test that can also be processed in part by a smartphone, with the testing itself being performed in a device about the size of a coffee mug. Its test costs about $2 to administer, compared to the current $10 per test to perform a NAAT-based assay in conventional laboratory. Johns Hopkins officials say they hope the test will encourage more testing for the often asymptomatic chlamydia should it eventually come to market.

Big Surge Forecast

Forecasting data projects a big surge in POC testing. Kalorama Information, the Rockville, Md.-based research firm, projects 6 percent year-over-year growth for much of the decade, outstripping growth in many of the world's other developed countries.

Inside The Lab Industry

Kalorama projects the POC market in the U.S. reaching $13.1 billion a year by 2018 (that includes over-the-counter assays, which are usually purchased by consumers to conduct testing at home). Demand for POC tests in developing countries such as India and China—where vast middle classes have sprung up in recent years with the means to afford health care services—has even much higher demand. According to the College of American Pathologsists (CAP), growth for some POC tests is as high as 30 percent a year.

Despite the fact that POC testing will almost certainly enjoy dramatic growth in the coming years, disadvantages to performing such tests compared to traditional laboratory testing remain.

Kalorama also noted that there has been an interest in the market for molecular POC testing, although the report observed that "platforms for molecular diagnostic POC testing need to be small, portable, potentially hand-held, easy-to-use, and inexpensive. They need to be fully automated from sample to answer, so that they can be used by individuals who are not highly trained in molecular diagnostics or in laboratory testing in general." And such tests would also require CLIA waivers as well.

Nevertheless, Kalorama noted that between 2009 and 2013, companies that are developing molecular POC or "near patient" tests have raised more than $650 million from investors and financings.

Some Disadvantages

Despite the fact that POC testing will almost certainly enjoy dramatic growth in the coming years, disadvantages to performing such tests compared to traditional laboratory testing remain.

According to a recent CAP report, "questionable quality can occur" when performing POC assays, "given the variety of educational and experience levels and turnover of staff that perform the tests." There is a risk that testing can be inadvertently performed on the wrong kinds of specimens (such as performing guaiac testing on nipple secretions instead of feces).

And even if a test is granted a CLIA waiver there is no guarantee that it is foolproof when conducted away from a traditional laboratory setting. "Simplicity is deceptive and there are many ways that staff can inadvertently generate a wrong result," the CAP said in its report, concluding that "just because it exists does not mean POC testing should be used in all situations. The need for comparability with central laboratory testing, efficacy, operational device and kit failsafes, management and oversight requirements, operator performance standards, economic indicators, and patient outcome data are all now considerations."

Takeaway: Improvements in technology and shifting health care markets means point-of-care testing is expected to grow significantly in the coming years. G2

CMTP Issues Draft Framework for Covering NGS Testing, *from page 1*

At the same time, the report suggested that labs may not be in the ideal position to advocate for their own products. "At issue is a growing flood of new genomic variants in need of study and a lack of economic and commercial incentives for testing companies and laboratories to perform the kinds of studies payers and health technology assessment groups generally expect to see," the report noted.

"NGS testing methods are potentially important new tools to enable clinical genomics and the realization of personalized medicine," said Donna Messner, a CMTP vice president and director, who led the guideline development effort, in a statement. "However, there is currently substantial uncertainty over future health plan coverage policy for genomics and how to accelerate evidence development for this testing."

"The lack of predictable coverage and reimbursement policies that anticipate the rapid emergence of new genomic tools could become a hindrance to cancer care."

— Sean Tunis, CEO, CMTP

Through its Green Park Collaborative, CMTP developed the guidelines in consultation with the laboratory, provider, and insurer sectors through a variety of phone calls and conferences held in the summer of 2014 and last spring.

The working group reached consensus on two specific points: Coverage should be provided for panels of up to 50 genes that are analyzed for a subset of five or more genes that are considered to be standard-of-care for use with a given diagnosis such as stage four lung adenocarcinomas and other forms of advanced cancers (although payers had expressed concerns about covering any panel with 50 or more genes at all). And whole exome and whole genome sequencing should still be considered investigational assays and therefore should not be covered by payers. Among the other recommendations in the framework:

- Payers should require laboratory accreditation through the College of American Pathologists, particularly for all NGS-related requirements mandated by that organization.
- The cost of performing NGS should not exceed the cost of individual sequencing of the target genes by other methods.
- Payers should consider compensating labs that submit new variant data to well-curated, public access databases of somatic mutations.

CMTP is now accepting public comments on the guidelines. The organization said it would use those comments and continued meetings with the major laboratory and payer organizations and the U.S. Food and Drug Administration to try to solidify more details for NGS-related coverage, data sharing from NGS testing, and even coverage of NGS-related off-label use for certain targeted cancer therapies that are employed as the result of the tests.

"The lack of predictable coverage and reimbursement policies that anticipate the rapid emergence of new genomic tools could become a hindrance to cancer care," said CMTP CEO Sean Tunis in a statement. "Getting agreement on guidelines for coverage of targeted NGS gene panels is a crucial first step toward more comprehensive and forward-looking policies for genomics in clinical medicine."

Takeaway: The CMTP is trying to provide some coherence for the lab and insurer sectors regarding coverage for NGS-based testing.

INDUSTRY BUZZ

NantOmics Acquires OncoPlex Diagnostics

A diagnostic firm connected with a Los Angeles billionaire making a run to remake cancer care has acquired a Maryland-based clinical laboratory that specializes in testing tumor cell proteins.

NantOmics acquired OncoPlex Diagnostics earlier this month. The terms of the deal were not disclosed. NantOmics and its affiliated companies have been providing funding to OncoPlex since 2008, and it had an undisclosed stake in OncoPlex prior to purchasing the remainder of its shares.

OncoPlex Diagnostics holds a proprietary capability to solubilize tumor cell proteins from FFPE tissue that can then be examined through mass spectrometry analysis, officials said. Its addition is expected to expand NantOmics' genomic decoding capability. The company also performs more commonplace molecular testing as well, including protein expression assays for breast, gastrointestinal and lung cancers, as well as HPV-linked testing for head and neck cancers.

The umbrella company, Culver City, Calif.-based NantHealth, raised $320 million last year, a record for a genomics company. Its Clinical Operating System platform is a combination of molecular science, near real-time patient signal monitoring and the use of large-scale data analytics.

"OncoPlex brings to NantOmics unique, proprietary technology that provides clinically relevant and highly accurate quantitative test results for patients with cancer," said Patrick Soon-Shiong, M.D., the founder of NantWorks, another NantOmics' affiliate, in a statement. "With this integration, we have added state-of-the-art discovery tools and a complementary array of molecular diagnostic services and tests. More importantly, we have enhanced our ability to deliver patient-specific pan-omic information and, ultimately, improve disease diagnosis and therapy."

Soon-Shiong, who is L.A.'s richest resident and a part owner of the Los Angeles Lakers basketball team, made his fortune through the founding of two pharmaceutical firms, Abraxis and American Pharmaceutical Partners, which he eventually sold for more than $9.1 billion. He also played a role in the creation of the drug Abraxene, which plays a significant role in fighting pancreatic cancer.

Takeaway: NantOmics and NantWorks have added a specialty laboratory to its genomic decoding repertoire. G2

References

Center for Medical Technology Policy
410-547-2687

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

College of American Pathologists
847-832-7000

Food and Drug Administration
888-463-6332

Health Diagnostic Laboratory
804-343-2718

Kalorama Information
240-747-3096

NantOmics
310-883-1300

NeoGenomics
239-768-0600

Premier, Inc.
877-777-1552

True Health Diagnostics
972-987-1390

Note the change of address effective immediately.

To subscribe or renew LIR, call now: 1-888-729-2315
(AAB and NILA members qualify for a special discount, Offer code: LIRNI1)

Online: www.G2Intelligence.com
Email: customerservice@plainlanguagemedia.com
Mail to: Plain Language Media, LLLP, 15 Shaw Street, New London, CT, 06320
Fax: 1-888-729-2315

Multi-User/Multi-Location Pricing? Please contact Randy Cochran by email at Randy@PlainLanguageMedia.com or by phone at 201-747-3737.

 Laboratory Industry Report (ISSN 1060-5118) is published by G2 Intelligence, Plain Language Media, LLLP, 15 Shaw Street, New London, CT, 06320. Phone: 1-888-729-2315. Fax: 1-855-649-1623. Web site: www.G2Intelligence.com.

Kelly A. Briganti, JD, Editorial Director; Barbara Manning Grimm, Managing Editor; Ron Shinkman, Editor; Stephanie Murg, Managing Director; Kim Punter, Director of Conferences & Events; Randy Cochran, Corporate Licensing Manager; Jim Pearmain, General Manager; Pete Stowe, Managing Partner; Mark T. Ziebarth, Publisher.

Receiving duplicate issues? Have a billing question? Need to have your renewal dates coordinated? We'd be glad to help you. Call customer service at 1-888-729-2315.