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HIGHLIGHTS

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Quest Diagnostics Has Published Enormous Lead Contamination Study

Quest Diagnostics is again using its enormous trove of patient data to shed light on a public health issue: lead contamination.

The New Jersey-based national laboratory published a study in the most recent issue of the *Journal of Pediatrics* indicating that lead contamination among children is prevalent throughout significant areas of the United States.

The study was released less than a year after a crisis of lead-tainted drinking water emerged in the city of Flint, Mich. Flint had the element leach out of its water pipes after a city manager appointed by the state's governor decided to switch water supplies in order to save money. Quest officials said the study was begun before Flint made headlines.

The Quest study was enormous: It involved more than 5.2 million tests of children conducted by the company between 2009 and last year. Of those, about three-quarters were blood-based assays.

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CMS Bars Theranos' California Lab from Medicare Program

Elizabeth Holmes dropped out of college to start up Theranos. Now Theranos and Holmes have been dropped from the Medicare program. Theranos has confirmed that the Centers for Medicare & Medicaid Services (CMS) had issued sanctions that included the loss of its CLIA certification for its laboratory in Newark, Calif., barring Medicare payments for any hematology and laboratory services performed at the Newark facility, and the concurrent barring of Holmes from being involved with laboratory operations for at least two years.

The company is also subject to a $10,000 daily penalty starting July 12 until it corrects all the deficiencies cited by the CMS in prior inspection reports.

Being barred from the Medicare program is one of the most serious consequences that can be experienced by a health care provider.

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CMS Bars Theranos' California Lab from Medicare Program, *from page 1*

Many hospitals that have been barred from participation have closed their doors altogether.

The Palo Alto-based Theranos engaged in the corporate version of a stiff upper lip, noting in a series of statements that it intended to carry on.

The fall from grace for Theranos began even more swiftly than its ascent.

"While it was obviously difficult to hear the outcome of the CMS findings, we will work non-stop to resolve the issues identified," the company said. It noted that its laboratory in Scottsdale, Ariz., was compliant with CLIA and would continue to operate. Any tests that may come through its handful of patient centers currently operating in California would be sent to an unnamed third-party reference lab for testing. Theranos did not say whether it intended to appeal the CMS decision, which could lead to a temporary stay of the sanctions. Given the congested state of the federal administrative law courts that handle such matters, an appeal could take a year or more to be resolved.

For now, Theranos stated it would continue on and perhaps even find a niche for its services other than consumer-friendly lab tests.

Theranos also confirmed that Holmes would not only remain at its helm as CEO, she would still deliver a widely anticipated presentation at the annual meeting of the American Association of Clinical Chemistry discussing how Theranos' testing platform and technology works.

And the company has suggested it would focus on areas other than lab testing. "[Our] research and development unit has developed many technologies that are not dependent on running a clinical laboratory," it said. "The company will continue to build infrastructure and build on its mission of improving access through affordable diagnostic testing, and its proprietary technologies and accessible business model. Improving access through innovative technologies is a universal need, with growth opportunities in global and domestic vertical markets."

The fall from grace for Theranos began even more swiftly than its ascent. After the company was valued last year at $9 billion and Holmes was the subject of a *New Yorker* magazine profile, an investigation by the *Wall Street Journal* concluded that Theranos testing platform, which claimed to perform hundreds of lab tests with just a few drops of blood, was barely functional. Eventually, the company confirmed that it was performing tests on other commercial lab platforms and that it had issued tens of thousands of test results that had been inaccurate. The CMS has so far rejected its plan of action to make corrections.

Takeaway: Theranos has suffered another huge blow against its attempts to remain an ongoing business concern.

Transgenomic Tries to Jumpstart Business Model Again

A shrunken and struggling Transgenomic will attempt to greatly expand its line of molecular-based cancer tests in the coming months in an attempt to jumpstart growth again.

The Omaha-based molecular lab said it would focus on greatly increasing the detection power of its primary testing platform, Multiplexed Improved and Complete Enrichment Co-amplification at Lower Denaturation temperature, known as ICE-COLD PCR. The platform focuses on amplifying mutant DNA particles at greater rates than non-mutant particles. It was introduced early last year.

Transgenomic said the test would be expanded to cover more than 200 different types of DNA mutations over the next 18 months, with about 10 new mutations introduced every six to eight weeks.

The company disclosed in a recent filing with the Securities and Exchange Commission that its stock was in danger of being delisted from the NASDAQ exchange for being below minimum shareholder's equity requirements.

In addition to expanding its portfolio of products, Transgenomic Chief Executive Officer Paul Kinnon believes there is a change in the business environment to potentially exploit.

"Transgenomic believes ... testing for liquid biopsies and precision medicine will move away from large centralized labs toward distributed labs in large and medium-sized medical centers, fueled by the continued adoption of next-generation sequencing platforms and improved bioinformatics systems, the desire to treat and diagnose patients more efficiently and faster, and with the restrictions and delays faced by large centralized labs in obtaining reimbursement from public and private insurers," he said in an email. "We believe these trends support our commercial strategy of broadly granting access to our ICE COLD-PCR products to a wide variety of partners, thereby enabling broader adoption of precision medicine as part of a decentralized model."

The company declined to disclose any current volume data, or projections of how the ambitious expansion of its testing platform would affect future volumes.

Meanwhile, Transgenomic is operating in an environment that has been decidedly hostile to its business operations. Its revenue for the first quarter of 2016, just $200,000, was $500,000 less than the first quarter of 2015. The company also posted a loss of $300,000. In 2011, its revenue was nearly $32 million. Last year, it decided to shut down its genetic assays and platforms business, focusing instead on licensing its technology. Last March, it announced it had suspended all patient testing at its facility in New Haven, Conn.

The company disclosed in a recent filing with the Securities and Exchange Commission that its stock was in danger of being delisted from the NASDAQ exchange for being below minimum shareholder's equity requirements. Transgenomic has filed a plan of correction that earned it another 180 calendar days before a delisting might occur; the earliest date that can now occur is Oct. 17.

Transgenomic's stock is currently trading at about 58 cents per share, down from more than $1.70 a share less than a year ago. Few investment banking firms cover the stock, but recent reports suggest that short positions against Transgenomic have decreased by more than a third in recent weeks.

Takeaway: A struggling Transgenomic is trying to make a spirited expansion of its products in order to return the company back to a growth mode.

Inside The Lab Industry

CMS's Proposed Gapfill Prices for Molecular Tests Would Lead to Big Reimbursement Cuts

The Centers for Medicare & Medicaid Services (CMS) published interim gapfill prices last month for new CPT codes for molecular tests introduced earlier this year. Although the pricing was for a fairly narrow range of specialty molecular tests—just 16 CPT codes in all—they still caused some consternation among some of the esoteric molecular testing firms, several of which had codes designated specifically for their leading assays.

"Unpredictability within the reimbursement process, particularly lack of coordination across MACs, makes it very difficult to invest in the space let alone run a company."

— Amanda Murphy, Analyst, William Blair & Co.

Most of the tests wound up having their preliminary prices cut, compared to their prior regionalized prices—in some cases as much as 85 percent. That's even if the regional prices had been in place for a significant period of time.

The prices would be placed on the 2017 Clinical Laboratory Fee Schedule if CMS grants final approval later this year, although labs and other parties will have a period to submit comments. The pricing has brought some disruption into the group of companies impacted by the pricing, many of which are publicly-traded startups.

"Unpredictability within the reimbursement process, particularly lack of coordination across MACs, makes it very difficult to invest in the space let alone run a company," observed William Blair & Co. analyst Amanda Murphy in a recent report. "Given ongoing reimbursement instability, potential for increased regulation, and payer scrutiny around clinical data, we believe it is becoming increasingly more difficult to commercialize diagnostic assays. Thus, we believe the companies most well-positioned are those with the funding and commercial infrastructure to consolidate and bring these assays to market," she added.

Not surprisingly, some laboratories and lobbying groups are up in arms. The Coalition for 21st Century Medicine, an organization that represents many molecular labs, suggested that the proposed prices were out of sync with the guidelines established by the Protecting Access to Medicare Act of 2014 (PAMA), whose rules were recently finalized by CMS.

"The proposed gapfill rates are inconsistent with rates established by commercial payers and the PAMA statute," the Coalition said in a statement. "Additionally, the PAMA statute sets a maximum of 10% reduction in payment for any test code in [2018] using the new market-based rate methodology."

For example, reimbursement for CareDx's AlloMap assay was proposed to be reduced 74 percent, to $732 from $2,821. That test helps predict the risk of acute cellular rejection in potential heart transplant patients.

Inside The Lab Industry

CareDx said that such a cut would be harmful to heart transplant patients. "We have already heard from concerned patients and doctors," said company Chief Executive Officer Peter Maag.

Another proposed cut would impact Genomic Health's Oncotype DX test for colon cancer. Such a test gives greater treatment options to patients who have been diagnosed with intermediate stage forms of the disease, along with evaluating their risk of recurrence.

Total Costs For Certain Molecular Tests

CPT Code	Test	National Limit Price
81412	9-Gene Ashkenazi Jewish Screen	$597.91
81432	Hereditary Breast Cancer Panel, 14 Genes	$622.53
81433	Hereditary Breast Cancer Duplications/ Deletions Panel	$159.48
81434	Hereditary Retinal Disorder Screen	$597.91
81437	Hereditary Neuroendocrine Tumor	$597.91
81438	Hereditary Neuroendocrine Tumor, Duplications/Deletions	$597.31
81442	Noonan Gene Screen	$597.91
81490	Vectra Screen	$586.50
81493	Corus CAD	$741.01
81525	Oncotype DX	$848.86
81538	Veristrat	$283.00
81540	bioTheranostics	$1,522.17
81545	Afirma	$2,240.16
0009M	VisibiliT	$132.86
0010M	4K Score	$260.00

Source: Centers for Medicare & Medicaid Services

CMS proposed a price of $848.86. That's 73 percent lower than the price Genomic Health is receiving from local coverage determinations made by individual MACs.

In a statement issued to *Laboratory Industry Report*, Genomic Health said that it believed the proposed rate "is based upon a flawed methodology that includes misinformed rates by local Medicare administrative contractors who do not process Genomic Health's claims.

In addition, the methodology does not take into account the factors set forth in Medicare law to establish payment amounts, such as market rates and resources. These factors were considered when the local MAC originally established the payment rate for the Oncotype DX colon cancer test in 2011, which has been revalidated on multiple occasions by numerous MACs paying Oncotype DX claims over the past five years."

CareDx noted that MACs Palmetto GBA and Noridian had supported its original higher price but that input from other MACs led to the cut.

Inside The Lab Industry

Another big hit came to Veracyte for its Afirma gene expression classifier test for thyroid cancer. The test can help patients and physicians decide whether a cancerous node requires total thyroid removal. Although the Afirma test received the highest-price among the assays on the list at $2,240.16, that remains far below the price Medicare has been paying based on local determinations: $3,200. The proposed pricing represents a cut of roughly 30 percent.

"We are disappointed by the proposed gapfill rate, which we believe does not accurately reflect the value that the Afirma GEC delivers to patients and the healthcare system," said Veracyte Chief Executive Officer Bonnie Anderson in a statement. "Further, our test was one of an entire group of precision medicine diagnostic tests whose preliminary reimbursement rates were reduced."

"We will work with the Coalition for 21st Century Medicine and other stakeholders as part of the comment period to convince CMS to maintain the well-established MAC rate for the Oncotype DX colon cancer test."

— Genomic Health

According to Veracyte officials, Noridian was the MAC that had previously been processing all Afirma claims. It supported the $3,200 pricepoint, but that opinion was not shared by the other MACs.

One test that went all but untouched: Myriad Genetics' Vectra DA assay to help predict the progression of rheumatoid arthritis and the threat of joint damage. Its pricing remained essentially the same at $587.

Murphy noted that PAMA would likely provided some needed clarity to the issue.

"While PAMA has caused angst around potential cuts to CPT codes, the perhaps under-appreciated positive from the legislation is that it will transition pricing power away from CMS and the MACs and provide much needed visibility into pricing," she observed.

Meanwhile, Genomic Health, CareDx and Veracyte said they would push to have CMS reconsider the proposed rates.

"We will work with the Coalition for 21st Century Medicine and other stakeholders as part of the comment period to convince CMS to maintain the well-established MAC rate for the Oncotype DX colon cancer test," Genomic Health said.

Anderson said that Veracyte would engage CMS directly and through lobbying groups, and was "optimistic that the final Medicare reimbursement rate for the Afirma GEC will match the current rate of $3,200. We believe that to do otherwise would be a significant step backwards for innovation."

Takeaway: Many esoteric laboratories are unhappy with the current proposed 2017 gapfill pricing proposed by the Centers for Medicare & Medicaid Services, and plan to persuade the agency to change its position.

Quest Diagnostics Has Published Enormous Lead Contamination Study, *from page 1*

According to Quest spokesperson Wendy Bost, the assays were part of routine blood testing conducted by physicians that contracted with Quest for diagnostic services. The data was de-identified.

> *"These alarming findings show that while our nation has made progress in addressing lead exposure, our public health successes are neither complete nor demographically consistent."*
>
> — Harvey W. Kaufman, Quest

The findings were sobering: Although lead levels declined during much of the study's timeframe, 3.1 percent of boys and 2.8 percent of girls still had blood levels higher than the guidelines set by the Centers for Disease Control and Prevention. But various communities in upstate New York, Ohio and Pennsylvania had much higher blood lead levels, often at double-digit percentages of the population tested, linked primarily to many older structures that contained lead-based paint. States such as Pennsylvania, Kentucky, Ohio and Connecticut had high-lead blood levels approaching or exceeding 7 percent. High lead blood levels in Mississippi more than doubled during the study, from 3.1 percent to 6.3 percent.

"These alarming findings show that while our nation has made progress in addressing lead exposure, our public health successes are neither complete nor demographically consistent," said Harvey W. Kaufman, Quest's senior medical director and a co-author of the study, in a statement. "We have a long way to go, both in terms of contaminated water and residual lead-based paint, to reduce disparities that put some of our children at disproportionate risk of exposure to lead."

The lead study was Quest's second one in little more than a year that focuses on public health on a national level.

In March 2015, Quest released a study about the levels of adult-onset diabetes among Medicaid and non-Medicaid expansion populations, showing a troubling increase in diagnosed cases of the disease in states that expanded Medicaid eligibility under the Affordable Care Act.

Quest has also released studies previous to that on trends in food allergies and cholesterol levels, although the sample size of the lead test is considerably larger. The company is also well-known for an annual study on drug usage.

Bost said Quest has a staff of about 650 physicians and doctorate holders who publish as many as 150 studies a year in peer reviewed journals and other publications. The company announces specific findings for its national studies, which are called Quest Diagnostics Health Trends. She added that the company would continue to release national-level studies through its Health Trends label, including a study about hepatitis being conducted jointly with the CDC.

In other news, Quest said it was moving its company headquarters from Madison, N.J., to Secaucus, N.J. when the current lease on its office space expires next year. It will also move approximately 600 employees engaged in support functions from a space in Lyndhurst, N.J., to Secaucus as part of the planned move. Quest employs more than 2,300 people in New Jersey.

Takeaway: Quest Diagnostics is continuing to use a trove of patient data and test points to publicize public health issues that are of concern to the United States.

INDUSTRY BUZZ

LabCorp Develops Companion Diagnostic for Roche Cancer Drug

LabCorp has introduced a new companion diagnostic intended to aid patients in their treatment of non-small cell lung cancer (NSCLC).

The test, called cobas®, is to be used in conjunction with the Roche-manufactured drug Tarceva. That drug is used specifically to treat patients who have an initial diagnosis of NSCLC that has metastasized into other parts of the body. It can be useful for treating patients whose cancer has certain epidermal growth factor receptor (EGFR) mutations.

The LabCorp test focuses specifically on whether patients have a deleted exon 19 or exon 21 in the EGFR in their tumors, which is an indicator that Tarceva would be effective. The assay can be performed either using blood or tumor tissue. It is particularly useful for patients who are unable to undergo a tissue biopsy. Tarceva sales totaled nearly $1.2 billion last year.

> *"LabCorp is pleased to add this important new test to our menu of world-class diagnostics."*
>
> — Marcia Eisenberg, chief scientific officer, LabCorp

"The FDA approval of the ... test ... offers a minimally invasive option for patients with NSCLC," said Uwe Oberlaender, who heads Roche's molecular diagnostics division. "Partnering with key labs ensures that patients can be tested conveniently."

NSCLC lung cancer is among the deadliest forms of the disease, with long-term survival rates for patients with metastasis around 1 percent. The five-year survival rate for the disease is much higher if the tumor is localized, but symptoms often do not present until the cancer is advanced.

The North Carolina-based LabCorp said it received approval for the test from the U.S. Food and Drug Administration on June 1 and that it was the first test of its kind being offered in the country. A company spokesperson declined to release the retail price for the assay, which is available through LabCorp directly and via its Integrated Oncology affiliate.

"LabCorp is pleased to add this important new test to our menu of world-class diagnostics," said Marcia Eisenberg, LabCorp's chief scientific officer. "Knowledge is power for patients and their physicians, and tests like this can help patients access targeted, personalized treatment."

Takeaway: LabCorp is offering a companion diagnostic to one of the leading drugs for treating NSCLC lung cancer.

References

Centers for Disease Control and Prevention
800-232-4636

Food And Drug Adminstration
888-463-6332

Genomic Health
650-556-9300

LabCorp
336-229-1127

Quest Diagnostics
800-222-0446

Theranos
650-838-9292

Transgenomic
402-452-5400

Veracyte
650-243-6350

William Blair & Co.
312-364-8951
amurphy@williamblair.com

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