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HIGHLIGHTS

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Cleveland HeartLab Issues Economic Benefit Study for Its Inflammation Test

Cleveland HeartLab has become the latest esoteric laboratory to make the pitch that its tests can save the U.S. health care system a load of money in the long run.

A new study issued by Cleveland HeartLab concludes its assay to detect cardiac inflammation could save nearly $181 million over five years if employed by a commercial health plan with 1 million lives.

About 720,000 Americans suffer heart attacks every year, of which 515,000 are first-time incidents. Another 800,000 suffer strokes, of which 610,000 are occurring for the first time. According to data from the American Heart Association, half of all heart attacks and strokes occur in individuals with normal cholesterol levels.

The test can detect biomarkers such as Myeloperoxidase, Lp-Pla2, and hsCRP, which are associated with cardiac inflammation and therefore a higher risk for heart attacks and stroke. The test costs between $25 and $50, according to Tim Baker, a Cleveland HeartLab spokesperson.

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Quest, Memorial Sloan-Kettering Collaborate on Oncology Research

In an effort to beef up its diagnostic oncology services, Quest Diagnostics is introducing a new and expansive molecular test panel and has teamed up with the Memorial Sloan-Kettering Cancer Center in New York City to seek more insight into testing results.

The alliance between the nation's largest lab and perhaps the most prominent oncology center in the United States will likely bolster Quest's plans to aggressively expand its molecular cancer assays in the coming years.

Under the terms of the arrangement, Memorial Sloan-Kettering will provide clinical analysis and treatment recommendations stemming from the results of OncoVantage, Quest's new 34-gene cancer test for tumor biopsies that was introduced earlier this month. Quest will furnish deidentified test data to Memorial Sloan-Kettering, which

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Cleveland HeartLab Issues Economic Benefit Study for Its Inflammation Test, *from page 1*

According to Cleveland HeartLab's study, using its assay could lead to interventions that prevent more than 2,000 nonfatal myocardial infarctions among health plan members over five years and prevent more than 1,800 nonfatal ischemic strokes—as well as the associated costs for treating such episodes. The lab claims that savings reach $3 per member per month during the fifth year of implementation, regardless of the size of the health plan.

"Traditional methods for assessing and mitigating risk are insufficient and may misclassify an individual's actual risk of a heart attack and death," said Marc Penn, M.D., Cleveland HeartLab's chief medical officer. "Routine inflammation testing helps identify individuals with previously unidentified risk so that steps can be taken to decrease vascular inflammation, improve their state of wellness, and lower their risk of a heart attack and death."

The testing data released by Cleveland HeartLab is similar to the cost propositions put forward by California-based CardioDx, which has released several studies indicating the economic effectiveness of using its Corus test on patients who present to their physicians with chest pains.

Takeaway: More esoteric laboratories are publishing data to make an economic case for utilizing their tests.

Bio-Reference Earnings Slowed Little by Winter

The severe winter slowed down Bio-Reference Laboratories, but not by much. The New Jersey-based Bio-Reference reported record revenues for its fiscal second quarter, ending April 30, as they reached $201.4 million, up 14 percent from the $176.5 million reported a year ago. Net income dipped slightly, down to $10.3 million, compared to $11.3 million in the second quarter of 2013, a drop of 9 percent.

Nevertheless, the company estimated that the severe weather during the first part of 2014 dragged down revenues by about $5 million and net income by about $1.4 million.

"Our net income during the current quarter, when adjusted for the impact of the weather, is comparable to where we were in the same quarter last year despite the changes in reimbursement and the added infrastructure from our investments in Florida and California," said Marc Grodman, M.D., Bio-Reference's chief executive officer.

Esoteric testing, led by the GeneDx division that focuses on cancer and woman's health testing, was up 23 percent and accounted for about 12.5 percent of revenue.

"The growth at GeneDx was fueled by our leadership position in exome analysis, the cutting edge and differentiating genetic service we provide, as well our growing volume of inherited cancer testing," Grodman said.

Grodman added that the reimbursement headwinds from Medicare appear to be behind it now, and he doesn't expect any significant changes again until 2017.

Test/patient volumes approached 2.4 million, up 14 percent. Amanda Murphy and J.P. McKim of William Blair & Co. observed that the growth "was exceed-

ingly better than the industry average of closer to 1% to 2%," and it would have hit 17 percent if the weather had been better.

Bio-Reference's numbers beat Wall Street's projections. As a result, its stock surged more than $6 a share, or more than 20 percent, to $32.74 when it released its earnings on June 5. Its price has since settled down to around $29 a share in trading on Nasdaq, still more than 10 percent above its pre-earnings price.

Murphy and McKim projected continued growth for the remainder of the year, with a strong ramp-up to occur during the fourth quarter. They bumped their year-end revenue projections up from $810 million to $816 million.

Takeaway: Esoteric testing continues to be the one reliable driver of growth in the laboratory sector.

Calloway Laboratories Makes Biggest Health Care Fraud Settlement In West Virginia History

Calloway Laboratories has agreed to pay nearly $4.7 million to settle allegations that it defrauded the West Virginia Medicaid program by overbilling for urinalysis testing.

The money will go both to West Virginia and the federal government, which had investigated Calloway jointly. It is the largest sum ever recovered from a provider in West Virginia history.

"By resolving this matter Calloway eliminates the financial uncertainty associated with litigation and is now well-positioned to focus on advancing its commitment to provide state-of-the-art clinical toxicology laboratory services to patients and providers nationwide," the Woburn, Mass.-based Calloway said in a statement it posted on its Web site late last month.

The lab had been accused by regulators of overbilling Medicaid by billing for medical reviews and pathology services it never performed. The alleged overbilling occurred between 2009 and 2013.

"Calloway Labs performed a type of medical review with every urine drug screen. Medical review is not covered by Medicare or West Virginia Medicaid. Medicare and West Virginia Medicaid paid claims for the medical review because Calloway submitted them under the code for covered pathology services," U.S. Attorney Booth Goodwin said in a statement issued by his office.

Calloway's brief statement indicated the issue was a disagreement about how services were ordered and performed and that the settlement did not include an admission of any wrongdoing. It also hinted the blame should be attributed to its prior management.

In March 2012 Calloway agreed to pay $20 million to Massachusetts regulators to settle charges of paying kickbacks in order to generate unnecessary urine tests for the state's Medicaid program. Later that year, Calloway's former chief executive officer and chief operating officer pleaded guilty to state fraud charges.

Takeaway: It can take years for a health care provider to get the misdeeds of prior managers behind them.

In Bid to Cut Down Overutilization, Palmetto Issues Coverage Advisories on GI Staining, Breast Cancer Testing

Keith Kaplan, M.D., recalled the day he encountered that might be best described as a huge stain on slide staining.

That was when he was practicing in the Midwest and a patient with suspected colorectal cancer went to Kaplan's large health care organization for a second opinion. A liver biopsy was ordered, with an outside lab performing special staining. Eighteen immunohistochemical stains were performed altogether.

"You may need to do two or three immunohistochemistries in a situation like that. Not 18, not six to eight times what is required," said Kaplan, who now practices in North Carolina and is best known as the creator of the *Digital Pathology* blog, which he has been publishing since 2007.

According to Kaplan, who has delved into the issue of special staining on his blog on occasion, overutilization of special staining indeed exists in gastric pathology, primarily in a bid to drive up revenue for the practice or laboratory performing it. The stains are reimbursed anywhere from $12.12 to $97.65 apiece, depending on how they are coded.

Kaplan may be the most outspoken in the lab sector on this particular issue, but he definitely is not alone.

Palmetto GBA, the Medicare administrative contractor (MAC), recently issued revised payment guidelines—its leadership prefers the term "education articles"—regarding special stains for gastrointestinal (GI) pathology, as well as for breast cancer assays.

Regarding the GI stains, Palmetto stated on its Web site that "the vast majority of conditions of the stomach on biopsy can be diagnosed by the use of the routine hematoxylin and eosin (H&E) stain alone. There is potential for either overutilization or under-utilization of these ancillary special stains. In most cases it is NOT reasonable or necessary to perform 'special stains' such as alcian blue (AB) - periodic acid schiff (PAS) to determine if clinically meaningful intestinal metaplasia is present. In addition it is not usually reasonable or necessary to perform special stains or immunostains (IHC) to determine the presence of *H. pylori*."

Palmetto suggested that special stains should be conducted on 20 percent or fewer gastric biopsies and that pathologists conduct occasional self-assessments in order to ensure that they do not exceed that threshold.

On the breast cancer issue, Palmetto observed that "based on recommendations from the College of American Pathologists, the American Society of Clinical Oncology, and the National Comprehensive Cancer Network, hormone receptor assays, estrogen receptor (ER), progesterone receptor (PR), and Her-2/neu are the only current biomarkers that demonstrate standardized value in breast

cancer pathology evaluation." As a result, Palmetto said it would no longer allow payments for Ki-67, PI3K, and gene expression assays, noting that "no proven standardized value has been established."

The Ki-67 gene is normally an indicator of overall prognosis and tumor aggressiveness, but given that five-year survival rates for breast cancer are more than 90 percent in stage two and more than 70 percent in stage three, it often is not needed.

"[It] never became the standard of care," said Robert Boorstein, M.D., who heads the ClasGroup, a New Jersey-based pathology consulting firm.

Elaine Jeter, M.D., Palmetto's medical director, said the organization had detected overutilization in the two areas and took the necessary steps to neutralize inappropriate practices. "Palmetto GBA and others are always using data analytics to identify where utilization may appear to be inconsistent with standards of care or other established practice guidelines," she said. "When we identify these scenarios we address the issues with education, claim reviews, and/or policy development depending on the nature and scope of the potential problem."

The reasons behind the variability in staining—and propensity toward its overuse—is complex.

The Government Accountability Office has also chimed in on the issue. In June 2013, it issued a report concluding that the use of stains among pathologists rose 400 percent among self-referring practices between 2004 and 2010. Even among those practices that did not engage in self-referrals, the number of stains rose by 150 percent.

Different Sides to Issue

The changes appear to have pitted the more outspoken members of the pathology community who believe less is more when it comes to making diagnoses, versus those who are chafing against what they see as outsiders telling them how to run their laboratories and practices.

Kaplan is firmly in the less-is-more camp.

"A couple of years ago, I had a colleague who told me he couldn't diagnose intestinal metaplasia in the esophagus without a stain," he recalled. "I advised him if that was the case, he shouldn't read those cases."

Boorstein acknowledged that while there is a wide variability in how stains are used, he also believes that multiple staining is not always necessary.

"If most pathologists are able to make the diagnosis without the special stains or immunohistochemistry, what does that tell you—that you can make the diagnosis without them," he said.

The reasons behind the variability in staining—and propensity toward its overuse—is complex. Kaplan believes it begins during medical residencies, when some pathologists are trained by other clinicians who have

tended to err toward staining. He also believes that some pathologists leaning toward a specific diagnosis but not completely sure will order the stain to be more certain.

However, other factors come into play down the line, including some patients asking for every deliberate test to confirm a diagnosis. But both Kaplan and Boorstein also believe that business considerations play a significant role.

"The places I have worked, that has not been an area of overuse, but [they] have not had a business model for overordering special stains," Boorstein said.

But Kaplan has experienced such overuse, including a large hospital system where he claimed overstaining was systemic. As a result, he often reported the stain as being noncontributory, which zeroed out payment for the stain's professional component. And he and other colleagues would remove patient charges if they did not believe they should have to pay for the stain.

"First and foremost, pathologists, lab administrators, and business managers saw a way to generate revenue," Kaplan said of the overutilization.

CAP Objections

No pathologists who are against Palmetto would speak on the record regarding the guidelines, although there has been some grousing about the change. In particular, there has been anger that issuing an advisory guideline intended to discourage claims submissions short-circuits the process for creating a local coverage determination. That is a far more onerous process. It requires the MAC to devise alternatives to denying coverage, to seek input and comments from stakeholders, and also allows legal challenges in administrative law court—all of which can take years to resolve.

That is among the reasons the College of American Pathologists has voiced strong concerns about the move. The lobbying group said in a statement that it "objects to Palmetto's continuing practice of using its Website to post articles that seem to establish new payment restrictions on pathology services without the benefit of those restrictions being vetted through the required local coverage determination process. The CAP will continue to advocate strongly with [Centers for Medicare and Medicaid Services] that its Medicare Administrative Contractors adhere to the established requirements of the local determination process to implement changes to existing Medicare payment policy."

Meanwhile, Kaplan believes that Palmetto will eventually focus on other areas of potential overutilization.

"I am pretty certain the prostate triple stain will be next," he said.

Jeter confirmed that her organization is looking at other potentially overused procedures.

Takeaway: Palmetto GBA's move toward restricting test processes it sees as overutilization may or may not be adopted throughout the sector, but it is creating a debate regarding how pathologists should practice and how local coverage determinations should be promulgated. G2

■ **Quest, Memorial Sloan-Kettering Collaborate on Oncology Research**, *from page 1*

will then provide an in-depth prognosis as well as potential treatment recommendations, including specific drug therapies.

"This commitment to advancing molecular diagnostics in both a clinical and research context is central to our selection of Quest as a partner," said Jose Baselga, M.D., Memorial Sloan-Kettering physician-in-chief.

Laboratories such as Quest have been introducing pricey—and presumably high-margin—molecular tests that require high levels of accompanying analysis in order to better guarantee that payers will cover their costs.

"By combining our broad market reach, which covers half the practicing physicians and hospitals in the United States, with Memorial Sloan-Kettering's deep experience in cancer care and molecular science, we hope to illuminate the best possible cancer treatment options for patients across the country," said Quest Chief Executive Officer Steve Rusckowski.

Although Quest officials declined to disclose the specific terms of the deal, a company spokersperson did say Memorial Sloan-Kettering would receive a percentage of the revenue for each OncoVantage assay, which retails for between $2,600 and $2,800, along with some additional licensing fees.

Memorial Sloan-Kettering has been flexing its oncology care muscles in recent weeks. Last month, it opened the Marie-Josée and Henry R. Kravis Center for Molecular Oncology in about 5,700 square feet of newly renovated laboratory space. The center was funded by a $100 million gift from financier Henry Kravis and his wife. A Quest spokesperson said the deal was not connected to the new molecular oncology arm.

Expansion aside, Memorial Sloan-Kettering's researchers have also been able to track mutations in more than 340 genes linked to various forms of cancer.

"This relationship will empower clinicians to improve their patients' health by identifying the best therapies for patients today and by identifying specific patients who may benefit from participation in clinical trials. The needs of tomorrow's patients will be addressed by the deeper knowledge base we are building and its potential to drive the basic science needed to discover new therapies," said Craig B. Thompson, M.D., Memorial Sloan-Kettering's chief executive officer.

The agreement will continue unabated when Quest plans to release a greatly expanded version of OncoVantage next year. That assay will track more than 300 different genes linked to solid tumor cancers. It will retail for about $4,000, or about a 50 percent premium over the existing OncoVantage test.

"Quest will wholly develop and validate the test," said spokesperson Wendy Bost, although she added that "Memorial Sloan-Kettering may advise us on which genes we may want to consider based on their vast experience in molecular medicine and cancer care."

Both Quest and Memorial Sloan-Kettering said they would jointly study the genetic data linked to the tests to help design more effective treatments in the future.

Takeaway: Quest is aligning itself with a premier cancer center to help ensure brisk sales of its new OncoVantage test. G2

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INDUSTRY BUZZ

Quest to Carry New Companion Assay for Treatment of Melanoma

Quest Diagnostics has introduced a test intended to aid in the treatment in the most aggressive—and deadly—form of skin cancer.

The test, THxID-BRAF, was developed by the French diagnostics firm bioMerieux, which has a U.S. subsidiary based in North Carolina. The test received approval from the U.S. Food and Drug Administration (FDA) last year. The assay is used to determine the genetic makeup of melanomas that afflict individual patients, particularly if they carry the BRAF V600E or BRAF V600K mutations. Both have responded positively to treatment with either Tafinlar or Mekinist, which are manufactured and distributed by GlaxoSmith-Kline and also received FDA approval last year.

The drugs are intended to treat patients whose melanomas are metastatic or unresectable.

Although most forms of skin cancer are easily treatable and rarely deadly, melanoma is the only form of the disease that will routinely infiltrate other parts of the body if left untreated. About 76,000 Americans are diagnosed with the disease every year. It kills about 9,700 each year. The five-year survival rate in the earliest stages of the disease exceeds 90 percent but fluctuates during the intermediary stages. The 10-year survival rates are as little as 40 percent at stage two.

"The addition of the THxID-BRAF test to our menu reflects our commitment to offering the most advanced dermatopathology testing available and to the field of precision medicine, which aims to improve outcomes based on a holistic clinical understanding of the patient," said Frederic Waldman M.D., Quest's medical director of cancer diagnostics. "The THxID-BRAF test further extends the services we provide for melanoma and other cancers across a continuum of care, giving physicians insights to help guide treatment decisions and empower better health. Because Quest reaches about half of the practicing physicians and hospitals in the United States, patients and providers will now have access to the THxID-BRAF test on a truly broad national scale."

Takeaway: Quest's decision to offer the THxID-BRAF assay is another indicator of the increasing importance of diagnostic tests that work in tandem with pharmaceutical regimens.

References

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800-682-2666

Bio-Reference Laboratories
800-229-5227

Calloway Laboratories
781-224-9899

ClasGroup Co.
917-312-3786

Cleveland HeartLab
866-358-9828

College of American Pathologists
847-832-7000

Memorial Sloan-Kettering Cancer Center
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Palmetto GBA
800-633-4227

Quest Diagnostics
800-222-0446

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