

LABORATORY



ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

SAFEWAY CUTS LAB COSTS BY 33% WITH “REFERENCE PRICING” STRATEGY

The national grocery store chain Safeway reduced its average price paid per lab test by 33% over a three-year period (2010-2013) by instituting a “reference pricing” strategy that encouraged non-union employees in its self-insured PPO plan to use lower-cost labs.

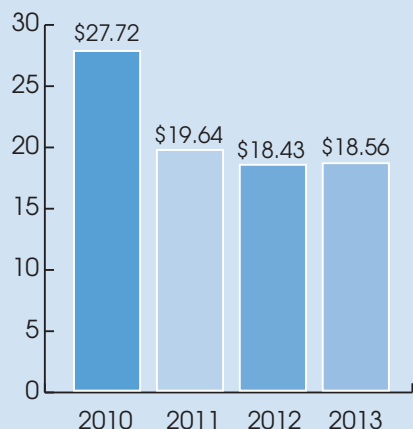
In 2011 Safeway established a maximum payment level (reference price) for 285 routine lab tests in each of its geographic markets. Employees selecting a lab charging less than or equal to this payment limit were subject only to the company’s usual copayment and deductible requirements. However, employees selecting a lab charging above the reference price were required to pay out-of-pocket for the full amount over the reference price and, in addition,

they had to pay the regular copayment and deductible requirements.

Safeway’s experiment with reference pricing was summarized in a study published in the online edition of *JAMA Internal Medicine* on July 25. “Reference pricing puts some, but not most, of the cost of a service on the patient, so it should steer people to lower-cost services rather than stopping them from seeking care at all,” according to lead author James C. Robinson, PhD, of the University of California, Berkeley.

More details on page 2.

Average Lab Test Price for Safeway Non-Union Employees



Source: JAMA Intern Med, July 25, 2016; “Association of Reference Pricing for Diagnostic Laboratory Testing”

GE GIVES UP ON DIGITAL PATHOLOGY JV

GE Healthcare and the University of Pittsburgh Medical Center (UPMC) are throwing in the towel on Omnyx LLC (Pittsburgh). Omnyx is the joint venture company formed by GE and UPMC in 2008 to develop and market a digital pathology system. Initially, Omnyx thought it could gain FDA clearance for its digital pathology system within two years (i.e., by mid-2010) for primary diagnosis. It also thought the U.S. digital pathology market would grow to \$2 billion within five years. However, both projections proved to be too optimistic. To date, no digital pathology system has received FDA clearance for primary diagnosis. *Continued on page 4.*

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SAFWAY CUTS LAB COSTS BY 33% (*cont'd from page 1*)

Lab tests accounted for 5.1% of Safeway's total medical care spending prior to the initiative. The focus of the Safeway reference pricing initiative was on 285 routine lab tests, representing 63% of all lab test claims for Safeway. The initiative excluded tests provided in the inpatient hospital and emergency department. Unionized employees and retirees were also excluded.

The Berkeley researchers used lab test claims data from Anthem as the control group, which was not subject to reference pricing. The final data set consisted of 344,413 lab tests used for Safeway employees and 1,781,640 tests used for Anthem enrollees over the 2010-2013 period.

According to the study, test prices charged by labs varied wildly. For example, in 2010, the price for the most commonly prescribed test, the basic metabolic panel, ranged from a \$5.75 to \$126.44, the highest price 22 times higher than the lowest. Prices for a lipid panel ranged from \$8.85 to \$74.92, while total PSA ranged from \$12.50 to \$88.75.

Safeway established a maximum payment limit (i.e., reference price) at the 60th percentile of the price range for each lab test. The company also gave employees online access to price lists by mobile phone and computer so they could compare prices charged by different labs in their area.

As mentioned earlier, employees who selected a lab that charged the reference price or less received full coverage. Those who chose labs that charged more had to pay the full difference themselves.

The researchers found that utilization of lab tests remained at an average of between 5 and 6 tests per year per employee throughout the study period. However, the implementation of the reference pricing policy dramatically changed where employees chose to get tested. Before 2011, 45.6% of tests were performed at labs that charged more than the reference price; by 2013, that percentage dropped to 15.6%.

Meanwhile, at the Anthem control group of patients, the use of higher-priced labs ranged from 73% to 84% during the study period and the average price paid per lab test increased slightly to \$29.72.

Characteristics of Patients and Lab Tests at Safeway, 2010-2013

| Characteristic | 2010 | 2011 | 2012 | 2013 |
|-------------------------------------|---------|---------|---------|---------|
| Total number of patients | 16,445 | 15,925 | 14,479 | 13,744 |
| Total number of lab tests | 92,606 | 89,635 | 82,638 | 79,532 |
| Avg. tests per patient | 5.6 | 5.6 | 5.7 | 5.8 |
| % Patients using higher-priced labs | 45.6% | 17.9% | 14.0% | 15.6% |
| Avg. price per test | \$27.72 | \$19.64 | \$18.43 | \$18.56 |

The study's authors concluded that Safeway's reference price program reduced spending on the 285 lab tests by \$2.57 million over three years

Source: *JAMA Intern Med*, July 25, 2016: "Association of Reference Pricing for Diagnostic Laboratory Testing"

compared with what would have been paid without the program. The researchers estimated that Safeway could have saved \$4.08 million if the reference test program had been applied to all lab tests.

Patients do not pay attention to the price being paid when their employer is paying, but with reference pricing they are incentivized to shop around, according to lead author Robinson. He said the key is for the health plan and/or employer to communicate reference price information to patients/employees.

Comparing Safeway Lab Test Prices vs. Medicare CLFS Rates

The Safeway study illustrates that Medicare's reimbursement rates can be viewed as either stingy or overly generous depending on how they are compared. When compared with the prices at lowest 5th percentile of labs (which presumably include the national labs), Medicare is paying roughly twice as much. But the Medicare program is getting a bargain when compared with the highest 95th percentile of labs (which presumably are hospital-based labs). The Safeway data also gives an indication of the huge effect that the exclusion of hospital lab prices will have in the PAMA private-payer calculations (*see story below*).

Distribution of Lab Test Prices Paid by Safeway in 2010 vs. Current Medicare CLFS Rates

| Test Name/CPT Code | 5th Percentile | Safeway 50th Percentile | 95th Percentile | Medicare NLA 2016 |
|-----------------------------------|----------------|-------------------------|-----------------|-------------------|
| Basic Metabolic Panel/80048 | \$5.75 | \$17.15 | \$126.44 | \$11.52 |
| Lipid Panel/80061 | 8.85 | 11.73 | 74.92 | 18.24 |
| Hepatic function panel/80076 | 5.56 | 11.32 | 85.14 | 11.13 |
| Iron test/83540 | 4.40 | 4.71 | 58.47 | 8.82 |
| Total PSA/84153 | 12.50 | 13.36 | 88.75 | 25.06 |
| Thyroid-stimulating hormone/84443 | 11.42 | 28.53 | 101.70 | 22.89 |
| Uric acid test/84550 | 3.07 | 3.47 | 30.60 | 6.16 |

Source: *JAMA Intern Med*, July 25, 2016: "Association of Reference Pricing for Diagnostic Laboratory Testing"

MOST HOSPITAL LABS EXCLUDED FROM PAMA REPORTING

New guidance issued by CMS on July 20 makes it clear that most, if not nearly all, hospital-based labs do not fall under the definition of an "applicable lab" required to collect and report their private-payer data to CMS. This means that CMS will be calculating new lab test fees based on information provided predominantly by the large commercial labs. "They missed the intent of the law by excluding the highest-paid part of the market," notes Alan Mertz, President of the American Clinical Laboratory Assn. (ACLA).

Both ACLA and the National Independent Laboratory Assn. had lobbied to have the term "applicable lab" defined by a lab's CLIA number. This would have meant that most hospital labs would have met the two thresholds for reporting: 1) greater than 50% of total Medicare revenues derived from the CLFS and PFS; and 2) at least \$12,500 in CLFS revenue collected during the six-month period January 1 to June 30, 2016.

However, as previously reported (*see LE*, July 2016, p. 1, 5-8), the Final Rule defines "applicable lab" by National Provider Identifier (NPI). As a result, any hospital lab that runs its billing through the same NPI as its hospital will not meet threshold #1 and therefore will not be required to report.

The July 20 guidance gives the following example:

A CLIA-certified hospital laboratory that performs laboratory services primarily for its hospital inpatients and hospital outpatients has the same NPI as the hospital. Laboratory services performed for non-hospital patients are billed using the hospital's NPI. In this example, the majority of Medicare revenues threshold and low expenditure threshold would be applied to the NPI of the entire hospital.

In this circumstance, it is unlikely that the hospital laboratory would qualify as an applicable laboratory because the majority of Medicare revenues for the NPI would be received from the hospital inpatient prospective payment system and/or hospital outpatient prospective payment system and not from the CLFS and/or PFS.

Only those hospital labs that have obtained their own unique NPI separate from the hospital's NPI will qualify as an applicable lab that must report their private-payer data. But the overwhelming majority of hospital labs do not have their own NPI. Instead they bill for their services through the main hospital's NPI and this means that most hospital-based labs will not be required to report their private-payer data to CMS under PAMA, notes Kathy Murphy, PhD, Senior Growth Advisor at Accumen Inc.

Furthermore, the latest CMS guidance clearly states that voluntary reporting from labs that are not applicable labs is not permitted.

The exclusion of data from the higher-priced hospital lab sector means that CMS's calculations will be mostly based on data from the biggest commercial labs and POLs (see table on page 5).

Mertz says ACLA is currently conducting a study to try to estimate how CMS's definition of "applicable lab" differs from the actual lab marketplace that the PAMA price-resetting was meant to reflect. The study may give ACLA ammunition to seek administrative or legislative changes to the way CMS defines the marketplace and calculates new rates. However, Mertz admits it will be challenging to get any changes made prior to the initial data collection period (already underway) and resulting CLFS price changes, which will be phased in over three years 2018 – 2020.

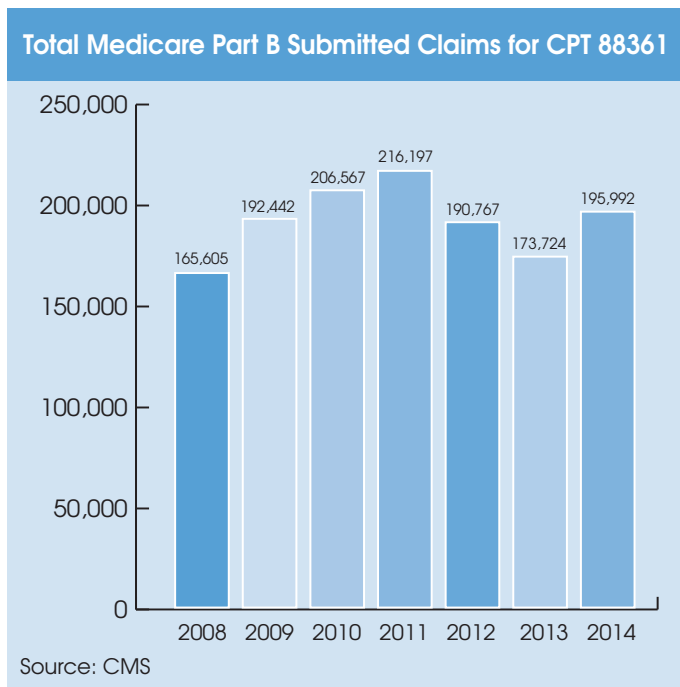
GE GIVES UP ON DIGITAL PATHOLOGY JOINT VENTURE *(cont'd from page 1)*

"UPMC and GE Healthcare can confirm plans to exit their joint Omnyx venture, primarily driven by variable global demand," according to a statement from GE Healthcare. "GE Healthcare will support existing customers through this transition and honor contractual commitments. GE

Healthcare and UPMC will continue their partnership in other areas of health innovation."

The adoption of digital pathology in the U.S. has been slowed by regulatory confusion, notes Keith Kaplan, MD, pathologist and publisher of The Digital Pathology Blog. He adds that many pathology groups and labs have been reluctant to invest in new technologies given the cuts to CPT 88305 and 88342.

The number of Part B submitted claims for digital immunohistochemistry (CPT 88361) has hovered around 200,000 for the past seven years, hitting a peak of 216,197 claims in 2011.



QUEST AND LABCORP PRICING LIKELY TO DOMINATE PAMA DATA

How much will private-payer pricing data from Quest Diagnostics and LabCorp influence the HCMS's calculations for repricing the CLFS? To answer this question, *Laboratory Economics* analyzed their share of volume of paid Part B services for Vitamin D Testing (CPT 82306) in 2014 (the latest year of available data). We chose Vitamin D because the Medicare Part B program paid a total of \$239 million for it in 2014, making it the single biggest code from the CLFS, in terms of Part B expenditures.

Medicare Part B paid a total of six million claims from more than 8,000 entities with their own NPI number in 2014. Combined, Quest Diagnostics and LabCorp accounted for a total of three million paid Part B claims for Vitamin D, accounting for 50% of the market. The top five lab companies (Quest, LabCorp, Sonic Healthcare, Opko/Bio-Reference and Spectra Laboratories) accounted for 3.5 million test claims, or 58% of the market, and the top 25 labs accounted for 3.9 million tests, or 65% of the market.

TOP 25 LABS FOR VITAMIN D TESTING BY PART B ALLOWED CLAIMS

| NPI | LABORATORY NAME | LOCATION | ALLOWED CLAIMS, 2014 |
|------------|-------------------------------------|----------------------|----------------------|
| MULTIPLE | QUEST DIAGNOSTICS | NATIONAL | 1,596,088 |
| MULTIPLE | LABCORP | NATIONAL | 1,434,266 |
| MULTIPLE | SONIC HEALTHCARE USA | NATIONAL | 236,900 |
| MULTIPLE | OPKO/BIO-REFERENCE | NATIONAL | 127,570 |
| MULTIPLE | SPECTRA/SHIEL MEDICAL LABORATORY | NATIONAL | 67,522 |
| 1427120336 | VISITING PHYSICIANS ASSOCIATION | TROY,MI | 40,877 |
| 1235234402 | ENZO CLINICAL LABS, INC. | FARMINGDALE, NY | 33,102 |
| 1518090448 | ATHEROTECH, INC. | BIRMINGHAM, AL | 32,946 |
| 1669515391 | ACCURATE DIAGNOSTICS LABS, INC. | EDISON, NJ | 32,699 |
| 1225110497 | ACCU REFERENCE MEDICAL LAB, LLC | LINDEN, NJ | 27,959 |
| 1710064811 | ACL LABORATORIES | WEST ALLIS, WI | 26,978 |
| 1235186800 | PATHGROUP LABS, LLC | NASHVILLE, TN | 26,383 |
| 1366543795 | NORTH SHORE LIJ LABORATORIES | NEW HYDE PARK, NY | 25,886 |
| 1255468328 | LENCO DIAGNOSTIC LABORATORIES | BROOKLYN, NY | 21,124 |
| 1295823540 | AMERICAN HEALTH ASSOCIATES | DAVIE, FL | 20,547 |
| 1053314146 | BIOTECH CLINICAL LABORATORIES | NOVI, MI | 19,245 |
| 1902131857 | PATHOLOGY ASSOCIATES MEDICAL LABS | SPOKANE, WA | 18,457 |
| 1720279805 | SCRIPPS HEALTH | SAN DIEGO, CA | 17,613 |
| 1790011054 | CALIFORNIA LABORATORY SCIENCES | SANTA FE SPRINGS, CA | 17,504 |
| 1043216682 | PRIMEX CLINICAL LABORATORIES | VAN NUYS, CA | 16,388 |
| 1740361690 | GAMMA HEALTHCARE | POPLAR BLUFF, MO | 16,287 |
| 1750364345 | DIAGNOSTICS LABS & RADIOLOGY | BURBANK, CA | 15,233 |
| 1477602639 | PACIFIC DIAGNOSTIC LABORATORIES | SANTA BARBARA, CA | 14,844 |
| 1043271539 | SMA MEDICAL, INC. | FEASTERVILLE, PA | 14,842 |
| 1215930987 | DIAGNOSTIC LABORATORY SERVICES, INC | AIEA, HI | 14,742 |
| | TOP 25 LABORATORIES | | 3,916,002 |
| | ALL LABORATORIES | | 5,981,208 |

Source: *Laboratory Economics* from CMS Provider Utilization Data for calendar-year 2014

QUEST DIAGNOSTICS MID-YEAR 2016 REVIEW

Quest Diagnostics (Madison, NJ) reported net income of \$298 million for the six months ended June 30, 2016, up 67% from \$179 million in the same period for 2015. Overall, Quest's reported half-year revenue was essentially unchanged at \$3.769 billion. Looking specifically at Quest's lab testing business: revenue was up 2.9% to \$3.565 billion, including 0.6% gained from acquisitions. On July 21, the company held a conference call with analysts and investors to discuss its mid-year results. Here's a summary of some key topics discussed:

Agreement with Safeway

Quest recently announced plans to open PSCs at 12 Safeway stores in five states (see *LE*, July 2016, p. 8). The PSCs will be adjacent to the pharmacy section at high-traffic Safeway supermarkets. The convenience of these in-store PSCs will help Quest reduce the number of unfulfilled test orders, which may average as high as 30% in the lab marketplace, according to CEO Steve Rusckowski.

High-Growth Tests

Rusckowski cited genetic testing, especially Quest's BRCA tests for hereditary breast cancer risk. He also mentioned companion diagnostics for hepatitis C. In addition, he said Quest's prescription drug monitoring tests for misuse of pain meds and opiates continue to grow.

Hospital Labs

"The strategy around hospitals is something that I believe will continue to be a great growth driver for us," said Rusckowski. He said that as hospital systems move away from fee-for-service to risk-based reimbursement, they are seeking low-cost providers. "[Hospitals] have a lot of other priorities and why would they put the next dollar of investment into laboratory when they have a good

Quest Diagnostics Mid-Year Financial Summary (\$ millions)

| | 6/30/2016 | 6/30/2015 | % Change |
|-------------------------------|-----------|-----------|----------|
| Total revenue | \$3,769 | \$3,764 | 0.1% |
| Operating cash flow | 464 | 327 | 41.9% |
| Capital expenditures | 104 | 117 | -11.1% |
| Free cash flow | 360 | 210 | 71.4% |
| Pretax income | 555 | 305 | 82.0% |
| Net income | 298 | 179 | 66.5% |
| Diluted EPS | 2.08 | 1.23 | 69.1% |
| Total debt | 3,842 | 3,736 | 2.8% |
| Cash & securities | 283 | 150 | 88.7% |
| Shareholders' equity | 4,569 | 4,344 | 5.2% |
| Bad debt % | 4.4% | 4.2% | 4.8% |
| Days sales outstanding | 47 | 44 | 6.8% |
| Est'd number of requisitions | 80.3 | 78.5 | 2.3% |
| Est'd revenue per requisition | \$44.40 | \$44.13 | 0.6% |

Source: Quest Diagnostics and *Laboratory Economics'* estimates

national leader nearby?"

Consequences of Likely PAMA Rate Cuts

The potential PAMA rate cuts expected in 2018 "could be considerable for small operators that are doing mostly routine testing in a small geography. And they're not billing out all the codes like we do through the clinical lab fee schedule for Medicare," noted Rusckowski.

LABCORP MID-YEAR 2016 REVIEW

LabCorp (Burlington, NC) reported net income of \$358 million for the six months ended June 30, 2016, more than double the \$173 million in the same period for 2015. Overall, LabCorp's reported half-year revenue was up 18.1% to \$4.799 billion.

Looking specifically at LabCorp's lab testing business: revenue was up 6.7% to \$3.25 billion, including 2% gained from acquisitions. On July 28, the company held a conference call with analysts and investors to discuss its mid-year results. Here's a summary of some key topics discussed:

Expansion of BeaconLBS

BeaconLBS has decreased out-of-network lab spending for UnitedHealthcare in Florida and improved test selection based on evidence-based guidelines, according to LabCorp CEO Dave King. BeaconLBS is a laboratory benefit management program owned by LabCorp.

"As we enhance BeaconLBS, as we extend its capabilities, as it becomes more and more integrated into EMR systems, I think we will move to new markets, and I think my perception is that United sees it as a valued tool to help them with correct lab test selection and management of their out-of-network spend. And we're both anxious to see it grow and expand into new markets," said King.

Sequenom Acquisition

On July 27, LabCorp announced plans to acquire Sequenom (San Diego, CA) for \$2.40 a share, or an equity value of \$302 million. Including Sequenom's outstanding debt puts the deal at an enterprise value of approximately \$371 million, which is 3.1 times the company's 2016 revenue estimate of \$120.5 million.

Sequenom operates a CLIA lab in San Diego that specializes in non-invasive prenatal testing. Its molecular laboratory-developed tests include MaterniT for high-risk pregnancies and VisibiliT for

LabCorp Mid-Year Financial Summary (\$ millions)

| | 6/30/2016 | 6/30/2015 | % Change |
|-------------------------------|-----------|-----------|----------|
| Total revenue | \$4,799 | \$4,062 | 18.1% |
| Operating cash flow | 467 | 310 | 50.6% |
| Capital expenditures | 138 | 103 | 34.5% |
| Free cash flow | 328 | 207 | 58.6% |
| Pretax income | 569 | 299 | 90.5% |
| Net income | 358 | 173 | 107.3% |
| Diluted EPS | \$3.46 | \$1.76 | 96.6% |
| Total debt | 6,055 | 6,787 | -10.8% |
| Cash & securities | 640 | 619 | 3.3% |
| Shareholders' equity | 5,313 | 4,770 | 11.4% |
| Bad debt % | 4.6% | 4.4% | 4.5% |
| Est'd number of requisitions | 72.0 | 69.0 | 4.4% |
| Est'd revenue per requisition | \$45.17 | \$44.15 | 2.3% |

Source: LabCorp and *Laboratory Economics'* estimates

average-risk. Sequenom reported a net loss of \$16.3 million on revenue of \$128.3 million for the year ended December 31, 2015. Earlier this year, Sequenom announced a restructuring that included laying off 110 employees, or 20% of its workforce, and closing its lab in Raleigh-Durham, North Carolina.

Potential Acquisitions of Hospital Outreach Labs?

"I think the history of hospital outreach acquisitions is mixed, because you worry about significant attrition, and you worry about now that the lab is not owned by the hospital anymore the ability to retain the work," noted King.

THERANOS PITCHES NEW “MINILAB” TO AACC AUDIENCE

Facing a two-year ban from owning or operating a laboratory scheduled to take effect on September 5, Theranos CEO Elizabeth Holmes seems to be repositioning the company so she can stay in charge. During an August 1 presentation to a standing-room-only crowd at the annual meeting for the American Association for Clinical Chemistry (AACC) in Philadelphia, Holmes ignored the company’s lab problems and instead introduced a new point-of-care test (POCT) system called the “miniLab.” Under what may become its new business model, Theranos seems to be transitioning itself more as a R&D-stage IVD vendor rather than as a lab operator.

But while other IVD vendors spend tens of thousands of dollars to buy floor space to advertise their products at the AACC convention, Theranos’ Holmes was given 90 minutes to address a packed AACC convention hall with what amounted to an info-commercial for her company’s new test system.

Why Did AACC Invite Holmes to Present?

Dr Andy Hoofnagle, MD, PhD, a member of the conference organizing committee, told the *Financial Times* that he and several of his colleagues had “fought really hard to prevent” Holmes from appearing but were overruled by the AACC president, Patricia Jones, PhD. “This conference is about peer-reviewed science — you don’t bring in advertisers and give them the stage at a scientific meeting,” said Hoofnagle, who is head of clinical chemistry at the University of Washington.

So why would AACC’s Jones invite Holmes to give a presentation? Well, Theranos did recently create a Scientific and Medical Advisory Board with eight members who are presumably well compensated. And four of them—Susan A. Evans, PhD, FACB; Ann M. Gronowski, PhD, DABCC; Larry J. Kricka, D. Phil, FRCPath; and Jack Ladenson, PhD, DABCC—were past Presidents of the AACC. Dr. Jones leadership position at AACC ends next year and we’ll have to wait and see if she becomes the fifth former-president from AACC to get on the payroll at Theranos.

Theranos has shut down its CLIA lab in California but continues to operate a second lab and four patient service centers in Arizona.

“These past presidents—while respected members of the association—hold no decision-making authority at AACC and did not have any impact on the decision to have Elizabeth Holmes speak about Theranos’ technology at the AACC Annual Scientific Meeting. This decision was made by the current leadership at AACC,” according to AACC President Janet Kreizman.

The Presentation

Holmes said the miniLab can run a broad range of assay methods (e.g., hematology, immunology, clinical chemistry, immunochemistry and nucleic acid amplification) simultaneously on a single miniature test platform—about 95 pounds and is about the size of a mini-refrigerator. She presented internal studies on miniLab performance data for 11 different assays, including potassium, lipid panel, HSV-2 and a test for the mosquito-borne Zika virus.

However, the performance data Holmes presented onstage was not independently verified, but instead relied on Theranos’ own internal studies. Furthermore, neither the miniLab system nor any associated assays have been approved by the FDA.

“We have a lot of work to do.... We now have to engage in peer-reviewed publication and we have to engage in third-party studies and we’re working to do that,” Holmes told the AACC audience.

However, *Laboratory Economics* notes that Theranos has been promising to have its testing technology validated by independent sources for a long time. For example, *LE* notes that it’s been more than one year since Theranos announced an agreement to have Cleveland Clinic perform comparative studies of Theranos’ testing technology versus traditional lab instruments. “No studies have

begun between Cleveland Clinic and Theranos to this point,” according to Eileen Sheil, Executive Director, Corporate Communications at Cleveland Clinic.

Audience Skeptical

Members of the AACC audience appeared to be skeptical of claims made by Holmes. During the question and answer period, there was loud applause when Stephen Master, MD, PhD, director of the central laboratory and chief of clinical chemistry at Weill Cornell Medical College, argued that the evidence presented by Holmes “fell far short” of the broad claims made by Theranos previously.

Holmes refused to discuss how the miniLab compared to the technology that Theranos has been using, saying this presentation was about introducing the company’s latest technology. “We know there are a lot of questions about the past and we will address those in the appropriate forum,” she said.

Theranos miniLab Years Behind Existing POCT Technology

Meanwhile, *LE* notes that Theranos’ miniLab looks a lot like a smaller desktop analyzer made by Abaxis Inc. (Union City, CA). Abaxis introduced its Piccolo chemistry analyzer to the lab marketplace in November 1995. The FDA-cleared Piccolo is about the size of a shoebox, weighs only 12 pounds, and offers the largest test menu (31 routine chemistry tests) of any POCT system on



Piccolo Chemistry Analyzer

the market. The system provides test results in approximately 12 minutes from small whole blood, serum or plasma samples. The Piccolo is distributed by Abbott in the United States and thousands have been placed in physician offices, hospitals, urgent care centers and pharmacies. Abaxis is also developing a new version of the Piccolo that will add high-sensitivity immunoassays to its test menu.

Heart Attack Patient Blames Theranos

Meanwhile, in a lawsuit filed July 15 in the U.S. District Court in Arizona (Case 2:16-cv-02373-SPL), an ex-customer alleges that inaccurate lab tests performed by Theranos directly led to him having a heart attack. The customer, identified only as R.C. in the lawsuit, says that in February 2015, he received orders from his physician to have a routine lipid and A1C blood panel to monitor his heart health. R.C. went to a Walgreen’s and had his blood drawn by a Theranos phlebotomist.

“Theranos tested the blood it drew from R.C.’s arm and sent normal results to R.C.’s doctor. Based on the normal lab test results, R.C.’s doctor recommended R.C. maintain his current medication regime and to return in one year,” according to the lawsuit.

But less than a month later, R.C. suffered a heart attack, leading to a hospitalization during which doctors had to implant two stents into his arteries. Lab tests performed during his hospitalization strongly suggested that the Theranos tests were inaccurate. Subsequently, Theranos “voided” R.C.’s Theranos test results, strengthening his concern that the company’s test results were in fact inaccurate.

R.C. is seeking class-action status for his case and more than \$5 million in damages. It’s at least the ninth civil lawsuit filed by an ex-customer against Theranos. Importantly, R.C.’s lawsuit is the first to allege Theranos’ inaccurate tests caused patient harm.

How Fast is Theranos Burning through its Cash?

With negligible revenue, 790 employees, huge office leases in California and Arizona, and rising legal costs, it may just be a matter of time before Theranos is forced into a massive restructuring to conserve cash, observes *Laboratory Economics*. Such a restructuring would align the company with the reality of its situation—a small troubled lab company with unproven testing technology.

STRATEGIES FOR INCREASING PATIENT COLLECTIONS

In 2011, less than 10% of revenue collected by Dallas-based AP lab ProPath came from patient collections. By 2013, that figure had risen to almost 15% and today hovers around 14%. The increase in patient collections is largely due to a multi-pronged effort focused on making it easier for patients to go online to ask questions and pay bills through tools such as email and a patient web portal, according to Jeanette Gray, Manager, Revenue Management and Contracts for the lab.



Jeanette Gray

Gray discussed strategies for increasing patient collections with Kurt Matthes during a July 21 teleconference sponsored by *Laboratory Economics*. Matthes is Vice President, Reengineering and Service for TELCOR (Omaha, NE), which specializes in software for point of care and laboratory billing.

ProPath, which provides pathology services for 22 North Texas hospitals and serves as a national AP and specialty testing lab, averages 68,000-70,000 patient statements each month. Prior to implementing a new billing system in 2011, the lab experienced significant challenges in collecting payment from patients. This was due to a number of factors, including use of an antiquated billing system, the growth of high-deductible plans and out-of-network issues such as plans paying the patient directly and no access to explanation of benefits.

The new billing system provided better visibility to outstanding accounts receivables, implemented a new patient statement format and allowed patients to go online to update their information, check balances and pay their lab bills. “Right now we average about 200 inquiries a month from patients, and 43% of those are updating their insurance information,” Gray says.

At the same time, ProPath developed a prepayment program for uninsured patients and developed patient collateral material for clients, which educated clients about participating and non-participating plans. The lab also implemented eligibility checks against Medicaid for self-pay hospital-based patients.

While a significant number of patients (45.2%) still send their payments by check through the mail, an increasing number (31%) now pay online using a credit card, and that figure is expected to go up. Almost 19% pay by phone using a credit card, and about five percent send a credit card payment through the mail.

Going forward, Gray anticipates that ProPath will decrease the pre-collections AR aging cycle from 120 days to 90 days. “The reason for that is that 90% of the patients who intend to make a payment will make that payment within the first 90 days,” she explains. “With the savings, we may start doing some pre-collection calls in-house and auto-faxing clients to obtain correct patient addresses.”

Common Problem

ProPath’s dilemma in collecting payment from patients is common among laboratories as well as other health care providers, notes Matthes. As employers shift to high-deductible plans and patients shoulder a larger share of out-of-pocket payments, labs are increasingly on the hook for getting patients to pay their copay or cost-sharing amount. While it may be acceptable to write off small amounts as bad debt, a policy of writing off all patient debt can land a lab in hot water with regulators.



Kurt Matthes

In fact, the Health and Human Services Office of Inspector General (OIG) has

long held that routine waiver of copayments is equivalent to an illegal kickback, which is a felony. Insurers also have cracked down on waivers of copays or cost-sharing and are becoming more aggressive in their enforcement of the copayment and deductible provisions in their contracts.

“Remember, you have to be able to prove you’ve attempted to collect from the patient,” advises Matthes. “If you can’t, you have a significant problem that could result in serious penalties for your laboratory.”

According to a 2015 survey conducted by the Kaiser Family Foundation and the *New York Times* medical bill survey, 64% of patients surveyed say they’ve had problems paying laboratory bills even though those bills represent just four percent of the total amount owed.

Why are labs less of a priority when it comes to paying medical bills? Primarily it’s due to a degree of separation between the lab and the patient, says Matthes – your provider knows who you are, but their patients don’t. What’s more, patients often don’t understand the testing ordered on their behalf.

To improve patient collections, labs should work to improve communication with patients and simplify statements. Labs should have multiple methods available for accepting payment, including patient portals for online payments and installment plan options. It also helps to provide an incentive discount (5% or 10% is typical) for early payments, he says, adding that you must ensure any discount offered is allowed by federal and state law.

Tips for Improving Patient Collections:

- Automatically mail or email a patient letter at the time a claim is billed to insurance, identifying the lab and explaining the patient’s liability;
- Have policies for what patient balances qualify for adjustments;
- Provide the opportunity for the patient to decline or approve testing your laboratory is going to perform when there is a lack of benefits coverage;
- Leverage services from a vendor to print and mail patient statements and perform bad address checking and correction;
- Allow patients to elect to receive bills via email;
- Work with ordering providers so they consistently deliver correct patient information—support this effort by providing metrics reflecting frequency of inadequate information;
- Automatically email or fax requests for patient insurance information; and
- Provide a client portal allowing easy access for clients to enter patient information that updates your billing solution.

Source: ProPath and TELCOR

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LAB STOCKS UP 7% YTD

Sixteen lab stocks have risen by an unweighted average of 7% year to date through August 10. In comparison, the S&P 500 Index is up 7.7%. The top-performing lab stocks so far this year are Exact Sciences, up 111%, Psychomedics, up 94%, and Enzo Biochem, up 46%. Meanwhile, LabCorp is up 13% and Quest Diagnostics is up 20%.

| Company (ticker) | Stock Price 8/10/16 | Stock Price 12/31/15 | 2016 Price Change | Market Capitalization (\$ millions) | P/E Ratio | Price/ Sales | Price/ Book |
|-----------------------------|------------------------|-------------------------|-------------------------|---|--------------|-----------------|----------------|
| Cancer Genetics Inc. (CGIX) | 2.03 | 3.30 | -38% | 33 | NA | 1.6 | 1.0 |
| CombiMatrix (CBMX) | 3.63 | 10.95 | -67% | 9 | NA | 0.4 | 0.4 |
| Enzo Biochem (ENZ) | 6.59 | 4.50 | 46% | 305 | 17.3 | 3.0 | 5.8 |
| Exact Sciences (EXAS) | 19.45 | 9.23 | 111% | 2,100 | NA | 33.3 | 7.7 |
| Foundation Medicine (FMI) | 24.56 | 21.06 | 17% | 864 | NA | 7.9 | 3.9 |
| Genomic Health (GHDX) | 28.75 | 35.20 | -18% | 954 | NA | 3.1 | 6.9 |
| Invitae (NVTA) | 8.95 | 8.21 | 9% | 279 | NA | 18.7 | 3.0 |
| LabCorp (LH) | 140.15 | 123.64 | 13% | 14,340 | 23.3 | 1.6 | 2.7 |
| Myriad Genetics (MYGN) | 19.70 | 43.16 | -54% | 1,380 | 13.3 | 1.8 | 1.8 |
| NeoGenomics (NEO) | 8.05 | 7.87 | 2% | 629 | NA | 3.6 | 3.1 |
| Opko Health (OPK) | 9.92 | 10.05 | -1% | 5,450 | 32.7 | 5.1 | 2.6 |
| Psychomedics (PMD) | 19.63 | 10.14 | 94% | 107 | 41.2 | 3.6 | 9.0 |
| Quest Diagnostics (DGX) | 85.36 | 71.14 | 20% | 11,870 | 14.9 | 1.6 | 2.6 |
| Rosetta Genomics (ROSG) | 1.06 | 1.23 | -14% | 22 | NA | 2.1 | 1.4 |
| Sonic Healthcare (SHL.AX) | 21.84 | 17.87 | 22% | 9,070 | 24.6 | 2.0 | 2.5 |
| Veracyte (VCYT) | 4.94 | 7.20 | -31% | 139 | NA | 2.6 | 4.1 |
| Unweighted Averages | | | 7% | | 23.9 | 5.7 | 3.7 |

Source: Capital IQ

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