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LABORATORY ECONOMICS

*Competitive Market Analysis For Laboratory Management Decision Makers*

## FLORIDA ATTORNEY GENERAL JOINS MEDICAID PRICING LAWSUIT

Florida Attorney General Pamela Jo Bondi is suing Quest Diagnostics and LabCorp to recover millions of dollars in overcharges she believes were collected from Florida's Medicaid Program over the past 13 years. Florida has 3.3 million Medicaid recipients making it the fourth largest state in terms of Medicaid enrollment.

The Florida Attorney General's Office investigated a whistleblower claim initially made by Chris Riedel and Hunter Laboratories in 2007. The Florida Circuit Court in Leon County recently granted the Attorney General's motion to unseal the case (#2007-CA-003549) for the purposes of filing an Intervention Complaint and proceeding with the action.

The lawsuit contends that Florida Medicaid regulations require labs to bill their lowest rates for services provided to Medicaid patients. Instead, the lawsuit alleges that Quest and LabCorp billed Medicaid some of their highest rates, while deeply discounting many of their fees to other customers. *Continued on page 5.*

## PFS FINAL RULE DELAYED UNTIL NOV. 27; CUTS EXPECTED FOR SOME KEY CODES

There is growing hope that a CMS proposal to link technical-component payment for 39 pathology codes to Hospital Outpatient Rates will be withdrawn from the Final Physician Fee Schedule Rule for 2014. Nonetheless, significant cuts are still expected for both the professional and technical components of several high-volume codes (including 88342, 88112, 88365, 88367 and 88368) as a result of CMS's "misvalued" code initiative. *Full details on page 4.*

## SUNSET OF EHR SAFE HARBOR WILL BRING BIG CHANGE TO LAB MARKETPLACE

The competitive landscape in the lab market is scheduled for a big change effective December 31, 2013. That's when the exception to the Stark Law and the Anti-Kickback Statute that permits hospitals and labs to donate electronic health records (EHRs) to physicians is set to expire. *Full details on page 8.*

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## MEDLAB FILES FOR BANKRUPTCY; SEEKS SALE OF ASSETS

Laboratory Partners Inc., also known as MedLab (Cincinnati, OH), filed for Chapter 11 bankruptcy protection on October 25, citing reimbursement reductions from Medicare and other payers. MedLab is hoping to restructure its $42 million in debt and raise cash by selling two of its three divisions—its long-term care division and its Terre Haute, Indiana-area lab business—through auctions in December and January. MedLab says it will continue to operate its laboratories and serve clients as it seeks the sale of these assets.

In order to provide funds to support its operations as it restructures, MedLab has obtained a $5 million credit line from one of its existing lenders, Marathon Special Opportunity Fund (New York City).

Laboratory Partners has hired Development Specialists Inc. (DSI-Chicago) to provide financial restructuring advice. DSI President Bill Brandt has become Chief Executive of Laboratory Partners. In a press release, Laboratory Partners said that a court-supervised auction sale of its long-term care division should occur in December 2013. The auction of its Terre Haute area lab business is expected to take place in January 2014.

If MedLab is unable to complete its contemplated asset sales within the next few weeks, the company might be forced to shut down or scale back its lab operations on or about December 23, 2013, according to a filing the company made with the Ohio Office of Workforce Development on October 21, 2013.

MedLab was formed in 2005 by Richard Daly and raised more than $70 million from the sale of stock and debt to private equity firms between 2007 and 2010. Its largest investors included Oxford Biosciences Partners, Marathon, Chrysalis Ventures, Fort Washington Private Equity and Primus Capital. MedLab used the funds to acquire small independent clinical labs in the Midwest that had primarily provided lab test services to nursing homes.

**MedLab Acquisitions**

| | *Location* | *Date* |
|---|---|---|
| Terre Haute Medical Lab | Terre Haute, IN | March 2007 |
| Pathology Associates of Terre Haute | Terre Haute, IN | March 2007 |
| Kilbourne Medical Lab | Cincinnati, OH | June 2007 |
| Medi-Lab | Lima, OH | October 2007 |
| Clinical Health Labs | Cleveland, OH | December 2007 |
| Suburban Medical Laboratory | Cuyahoga Falls, OH | January 2008 |
| Biological Technology Labs | St. Louis, MO | September 2008 |

Source: *Laboratory Economics*

MedLab currently has 1,034 employees, including 794 employees at its nursing home lab business. Another 221 employees work at MedLab's physician-office client business or its hospital lab business based at Union Hospital in Indiana. In total, MedLab performs approximately six million lab tests per year. Assuming that MedLab receives an average of $15 per test would suggest the company has annual revenue of approximately $90 million.

Earlier this year, MedLab raised funds by selling a portion of its physician-office client business to LabCorp for $10.7 million in cash plus an earn-out payment of up to $1.2 million. MedLab used the proceeds to help pay off some of its debt and to fund operations.

MedLab says reimbursement pressure pushed it into bankruptcy, including Medicare's 3% cut to the clinical lab fee schedule on January 1, 2013, followed by the 2% sequestration cut on April 1. MedLab also cited Medicare's 50% cut to the technical component of CPT 88305 and said that some commercial payers have likewise made cuts. Blue Cross Blue Shield of Mississippi announced a 25% cut to pathology services on May 15, 2013, and Aetna announced that it was lowering its pathology rates to 45-50% of Medicare on July 1, 2013, according to the bankruptcy filing.

MedLab's debts include a $21.6 million secured loan from a group of lenders led by Bank of New York Mellon Corp. and Marathon Special Opportunity Fund. The company also owes more than $20 million in unsecured debt.

On the top of its list of unsecured creditors are several individuals who sold their labs to MedLab back in 2007. The former owners of Terre Haute Medical Lab and Pathology Associates of Terre Haute—M. Bashar Kashlan, MD, and Gerald J. Longa, MD—are each owed $3.16 million in unsecured notes. In addition, Paul Kilbourne, former owner of Kilbourne Medical Lab, is owed $2.5 million from an unsecured note, according to the bankruptcy filing.

Drs. Kashlan and Longa have each filed lawsuits against Laboratory Partners Inc. (aka MedLab). Kashlan and Longa sold their labs—THML and PATH—to Laboratory Partners in March 2007 for a combination of cash and promissory notes. Principal and interest on the notes was due to be paid off in full on May 1, 2013. Kashlan and Longa claim that Laboratory Partners has breached its contract by failing to pay interest and principal due on the notes. Kashlan and Longa are each seeking $3.16 million in principal and interest due on the notes plus another $245,000 in attorney's fees and other costs from Laboratory Partners.

**MedLab: List of Top 12 Unsecured Creditors**

| | |
|---|---|
| M. Bashar Kashlan, MD | $3,159,816 |
| Gerald J. Longa, MD | $3,159,816 |
| Paul Kilbourne | $2,451,827 |
| Fort Washington Private Equity | $2,059,586 |
| Oxford Bioscience Partners | $1,590,860 |
| Primus Capital Fund | $1,458,587 |
| Chrysalis Ventures | $1,236,670 |
| Indiana Investment Fund | $1,164,917 |
| Thermo Fisher Scientific | $512,200 |
| Tri-State Growth Capital Fund | $333,702 |
| Abbott Laboratories | $328,613 |
| Quest Diagnostics | $310,333 |

Source: *Laboratory Economics* from bankruptcy filing

## QUEST WINS EXCLUSIVE CONTRACT WITH QUALCARE

QualCare (Piscataway, NJ) has selected Quest Diagnostics as its exclusive commercial lab effective January 1, 2013. QualCare services over 800,000 members in self-funded PPO, HMO and POS plans in New Jersey, New York and Pennsylvania. QualCare is owned by 16 non-profit hospitals and physician-hospital organizations. QualCare currently has lab contracts with more than 20 labs, including LabCorp, Bio-Reference Labs and Shiel Medical Lab. Financial terms of the new contract with Quest were not disclosed, but Kevin Joyce, vice president of network and delivery systems at QualCare, expects a 15% to 20% reduction in lab spending. QualCare processes about $1 billion in medical claims per year, and lab testing accounts for about 3% to 5% of that spending.

**CUTS EXPECTED FOR SOME KEY CODES** (*continued from page 1*)

Release of the Final Rule has been delayed until as late as November 27 because of the government shutdown.

CAP, ACLA and the rest of the lab and pathology industry have lobbied hard against the proposed HOPPS caps which would cut an estimated $500+ million in Medicare expenditures on pathology technical services. A bipartisan group of 40 Senators has urged CMS to reconsider the proposed cuts. The industry has made a strong case and there is a good chance that the HOPPS caps will be delayed or not implemented at all.

However, pathology rate reductions are still likely for several key codes as a result of CMS's "misvalued" code initiative. At the request of CMS, the AMA Relative Value Update Committee has been analyzing the relative value units (RVUs) for CPT codes 88342, 88112, 88365, 88367 and 88368. CAP, which has representation on the RVU Committee, has stated that it expects the Final 2014 Rule to include cuts to both the PC and TC components of all these codes.

The degree of the expected cuts is unknown, but could be substantial. Remember, the RVU Committee put CPT 88305-TC under review in 2012, which resulted in a devastating 52% reduction effective January 1, 2013. All together, the five codes under this year's review represent nearly half a billion dollars of annual Medicare expenditures.

CPT 88342: Both the PC and TC rates for CPT 88342 are likely to change next year through the use of a new add-on code to report each additional antibody tested on a patient sample. The first CPT 88342 would be billed at one rate, while additional 88342's would be billed at a lowered rate. Medicare spent $269 million on CPT 88342 in 2012.

CPT 88112: The TC and PC components for CPT 88112 (Cytopathology, cell enhancement technology) are under review because CMS identified them as high-expenditure codes that have not been reviewed since 2006. Medicare spent an estimated $89 million on CPT 88112 in 2012.

CPT 88365, 88367 & 88368: The PC and TC rates for CPT codes 88365-88368 may change to ensure the appropriate relativity to CPT codes 88120 and 88121. CMS is concerned that physicians may be reporting in-situ hybridization services (e.g., "FISH" testing) incorrectly where multiple units of each code are reported. Medicare spent approximately $90 million on CPT codes 88365-88368 in 2012.

## Pathology Codes Likely to be Cut in 2014 under "Misvalued" Code Initiative

| Code (Description) | 2012 Volume | 2012 Expenditures | 2013 PC Rate | 2013 TC Rate | 2013 Global |
|---|---|---|---|---|---|
| 88342 (Immunohistochemistry) | 4,901,522 | $268,736,429 | $40.16 | $64.09 | $104.25 |
| 88112 (Cytopath cell enhance tech) | 1,330,460 | $88,619,788 | $58.18 | $51.37 | $109.55 |
| 88368 (FISH-manual) | 376,698 | $53,476,640 | $61.58 | $170.46 | $232.04 |
| 88367 (FISH-computer assisted) | 239,574 | $30,364,638 | $59.88 | $198.35 | $258.23 |
| 88365 (FISH-each probe) | 65,020 | $5,055,801 | 58.18 | 120.44 | 178.62 |
| Total | 6,913,274 | $446,253,296 | | | |

Source: *Laboratory Economics* from CMS

 

**FLORIDA AG JOINS MEDICAID PRICING LAWSUIT** (*cont'd from page 1*)
The lawsuit says that Quest has been paid $75 million by Florida's Medicaid program over the past three years, while LabCorp has been paid $52 million over the same period.

The lawsuit notes that the "Florida Medicaid Provider General Handbook" contains the following language:

> **What the Provider May Charge For Services**
> The provider's charges for services billed to Medicaid must not exceed the provider's lowest charge to any other third party source for the same or equivalent medical and allied care, goods, or services provided to individuals who are not Medicaid recipients.
>
> **Reimbursement For Services**
> Medicaid reimbursement for services is the lesser of the Medicaid fee or the provider's usual and customary charge, except for cost-based or capitation reimbursed providers.

In addition, the lawsuit quotes Florida law (59G-5.110(2)), also known as the "lowest charge rule," which became effective May 9, 1999:

> Charges for services or goods billed to the Medicaid program shall not exceed the provider's lowest charge to any other third party payment source for the same or equivalent medical and allied care, goods, or services provided to persons who are not Medicaid recipients. Any services or goods customarily provided free of charge to patients may not be billed to Medicaid when provided to Medicaid recipients. Any payment made by Medicaid for services or goods not furnished in accordance with these provisions is subject to recoupment and the agency may, in such instances, initiate other appropriate administrative or legal action.

The lawsuit alleges that Quest and LabCorp each charged Florida Medicaid far more than many other non-Medicaid payers. For example, under a contract with the U.S. Dept. of Veterans Affairs, Quest charges $3.98 for CPT 80053 (comp. metabolic panel), but the company receives $10 from Florida Medicaid for the same test, according to the lawsuit.

In another example, the complaint contends that, in 2005, LabCorp submitted claims to the Florida Medicaid program with billed amounts of $50 for CPT 85025 (complete blood count) and accepted the maximum fee schedule amount of $7.20. At the same time, LabCorp had a contract with the Florida County Health Departments to serve non-Medicaid patients that paid $1.25 per CPT 85025, according to the lawsuit.

Attorney General Bondi is demanding three times the amount of the State of Florida's actual damages from Quest and LabCorp for the period January 2000 through the present. In addition, AG Bondi demands that both companies each be assessed civil penalties of $10,000 for each false claim submitted to Florida Medicaid during the past 13 years.

There is additional risk for Quest and LabCorp beyond the lawsuit because the Affordable Care Act says that any healthcare provider convicted of billing fraud can be automatically excluded from all government programs.

 

The Florida Medicaid Clinical Lab Fee Schedule is currently set at approximately 70% of national Medicare rates. The table below compares these rates to the rates that Quest and LabCorp currently charge the U.S. Department of Veterans Affairs in Florida, according to the lawsuit.

"We are aware of the allegations made in the case in Florida brought against us by a competitor, and the Attorney General's decision to intervene. The allegations are without merit, and we look forward to presenting our case. Our testing services are priced appropriately, and we are firmly focused on serving the needs of our patients in Florida," according to a statement from Quest.

### Pricing Comparison: Medicare vs. Florida Medicaid vs. Quest Diagnostics and LabCorp

| Test Name | CPT | 2013 Medicare Fee Schedule | 2013 Florida Medicaid Fee Schedule | Vet. Admin. Quest Fee | Vet. Admin. LabCorp Fee |
|---|---|---|---|---|---|
| Comp. Metabolic Panel | 80053 | $14.53 | $10.00 | $3.98 | $3.50 |
| Lipid Panel | 80061 | 18.42 | 9.50 | 8.26 | 5.50 |
| Basic Metabolic Panel | 80048 | 11.63 | 8.00 | 3.18 | 3.00 |
| Hepatic Function Panel | 80076 | 11.23 | 7.50 | 3.05 | 3.00 |

Source: Medicare Part B Lab Fee Schedule 2013; Florida Medicaid Lab Fee Schedule 2013; and State of Florida ex rel. Hunter Laboratories, LLC and Chris Riedel vs. Quest Diagnostics, et al. (case: 2007-CA-003549)

Riedel and Hunter Labs filed at least seven whistleblower cases against Quest and/or LabCorp between 2005 and 2008, including their case in California which was resolved in 2011 and resulted in approximately $300 million of total settlements. As whistleblower, Riedel is entitled to 15% to 30% of any settlement proceeds.

### Status of 7 Medicaid Whistleblower Lawsuits

| State | Medicaid Enrollment | Whistleblower Lawsuit Filed | State Intervene? | Defendants | Status |
|---|---|---|---|---|---|
| California | 6.7M | 2005 | YES | Quest, LabCorp and 7 smaller labs | Settled in 2011: Quest paid $241M; LabCorp paid $49.5M |
| Florida | 3.3M | 2007 | YES | Quest, LabCorp | Florida Attorney General intervened in November 2013 |
| Michigan | 2.0M | 2008 | YES | Quest | Quest's motion to dismiss denied; in discovery phase |
| Georgia | 1.9M | 2008 | NO | Quest, LabCorp | Awaiting court decision on motion to dismiss |
| Massachusetts | 1.4M | 2007 | NO | Quest | Quest has filed a motion to dismiss that is scheduled to be heard in mid-January. |
| Nevada | 341,000 | 2007 | NO | Quest | Nevada Supreme Court is reviewing Quest's Summary Judgment Motion and has stayed the trial until it comes to a decision. |
| Virginia | 900,000 | 2007 | NO | Quest, LabCorp | Virginia Judge dismissed suit; amended lawsuit filed on Nov. 8, 2013. |

Source: *Laboratory Economics* from lawsuits

# JUDGE DISMISSES VIRGINIA MEDICAID LAWSUIT; RIEDEL FILES AMENDED COMPLAINT

On October 25, A Virginia federal judge dismissed a whistleblower suit filed by Chris Riedel that charged Quest Diagnostics and LabCorp with fraud for overcharging the state's Medicaid program. "I cannot find a violation here because the regulation doesn't put a requirement on providers," according to U.S. District Judge Gerald Bruce Lee. Judge Lee dismissed the case in its entirety, but gave Riedel the opportunity to file an amended lawsuit, which he did on November 8.

Riedel's lawsuit, originally filed in 2007, alleged that Quest and LabCorp "made false claims for payment of Medicaid-covered laboratory tests by falsely representing that the fees being charged were no greater than the maximum fees payable pursuant to Virginia regulations." The lawsuit contends that labs are required to bill the Virginia Medicaid program their most favorable rates. However, Quest and LabCorp allegedly billed the state's Medicaid program at its published fee schedule rates, while offering the same tests to physicians, hospitals, HMOs and GPOs at deeply discounted rates that were sometimes below cost.

Riedel's case hinges on the interpretation of regulations from Virginia's Department of Medical Assistance Services (DMAS) that state "Payment for [laboratory services] shall be the lower of the state agency fee schedule…or actual charge (charge to the general public)." 12 VAC 30-80-30.

Riedel interprets this to mean that a lab can charge any customer (physician, hospital, HMO, GPO, etc.) any price for lab tests, so long as Medicaid gets the same price.

Quest and LabCorp argued that the regulations do not require healthcare providers to bill DMAS their most favorable rates. Instead, the regulations put the onus on DMAS to pay the lowest prices, according to the companies' arguments during the hearing.

Riedel and his attorney's argued that the defendant's interpretation of the law would allow them to charge Virginia's Medicaid system any exorbitant price they wanted without recourse.

"The amount that is charged has to be the amount charged to the general public," according to Riedel's lawyer Eric Buescher. "The reason it's a false claim is they don't provide the same discounts to the commonwealth as other clients. The lab can offer whatever discounts it wants to any private client it wants as long as Medicaid derives the same benefit."

Judge Lee sided with Quest and LabCorp's argument that the regulations only require the Medicaid program to pay the lowest rate. In addition, the judge stated that Riedel was not able to provide even one example of a false claim filed by either lab to Virginia Medicaid.

Riedel has filed an amended complaint. "The original complaint was six years old. We have a lot more specific information now," Riedel tells *Laboratory Economics*. It is now up to Judge Lee to decide whether or not to let the amended complaint proceed.

"We are pleased with the Court's decision and believe it was appropriate. Our testing services are priced appropriately, and we comply with the laws and regulations governing our business," says a spokesperson from Quest.

**SUNSET OF EHR SAFE HARBOR** (*continued from page 1*)

The national labs have aggressively used EHR donations as a marketing tool for winning and keeping physician office business since initial publication of the safe harbor in August 2006. In order to stay competitive, smaller labs have been compelled to provide EHR donations as well. The competitive pressure to provide EHR donations has added a significant layer of cost to the budgets of all labs, both big and small, over the past seven years. *Laboratory Economics* estimates that it is costing labs between $400 and $800 per month per physician client to provide them with an EHR (covering 85% of the cost of a certified EHR as permitted by the safe harbor).

Earlier this year, CMS and OIG each issued proposed rules that would extend the Stark Law exception and safe harbor protections for EHR donations for another three years to the end of 2016. However, both agencies said they were considering extending the exception to cover only hospitals, group practices, prescription drug plan sponsors and Medicare Advantage plans, but not laboratory companies.

In its proposed rule, issued April 1, 2013, OIG said:

> *We are considering excluding suppliers of ancillary services associated with a high risk of fraud and abuse, because donations by such suppliers may be more likely to be motivated by a purpose of securing future business than by a purpose of better coordinating care for beneficiaries across healthcare settings. In particular, we are considering excluding laboratory companies from the scope of permissible donors as their donations have been subject of complaints.*

CMS and OIG both submitted their final EHR rules to the White House Office of Management and Budget (OMB) in early November and a final rule is expected to be published in late November/early December.

The lab-physician client relationship will come under strain next year if, as expected, labs lose the EHR donation safe harbor. If not extended, physicians will be required to pay full charge for the EHR, notes Jane Pine Wood, attorney at McDonald Hopkins. The payments will be made to the EHR vendor, because almost all of these arrangements are between the physician practice and the vendor, she adds.

Path groups and labs are currently making the donation payment to EHR vendors covering 85% of the cost of EHRs for physician clients. Next year, physicians will in all likelihood need to take over this expense, which could add up to $5,000 to $10,000 in annual software license fees per physician. A 10-doctor group, for example, will be faced with as much as $100,000 per year in new expenses.

Quest Diagnostics will be in a unique position because it has installed its own EHR software (Care360) at its physician office clients. Quest currently charges physician clients that use its Care360 EHR less than $100 per month for software license and support. This fee could be raised to more than $600 per physician per month if the EHR donation safe harbor expires.

On the bright side, expiration of the EHR donation safe harbor will remove a large cost-of-doing-business expense from lab budgets next year and help offset some of the pressure from Medicare rate reductions, notes *Laboratory Economics*.

## SPECTRA TO ACQUIRE SHIEL MEDICAL LABORATORY

Spectra Laboratories (Rockleigh, NJ) has agreed to buy Shiel Medical Laboratory (SML-Brooklyn, NY) for an undisclosed amount. The transaction is expected to close in December.

Founded in 1919, SML is the largest privately held clinical lab in New York. Its main lab (50,000 sq. ft.) is located in the Brooklyn Navy Yard and employs more than 630 people. The company provides a full menu of clinical and anatomic pathology tests throughout the greater New York City metropolitan area.

SML will operate as a division of Spectra Labs, but will maintain its operational independence. The lab staff and executive team at SML is expected to remain intact, including Chief Executive and owner Jack Basch.

Spectra is a subsidiary of Fresenius Medical Care. Fresenius is a publicly-traded, multi-billion dollar global health care company that provides dialysis products and services, clinical nutrition and infusion therapies, hospital operation and management services and home therapies. Spectra specializes in dialysis patient testing and operates major labs in Rockleigh, NJ and Milpitas, CA.

## LEVINE LEICHTMAN BUYS GENOVA DIAGNOSTICS

Los Angeles private equity firm Levine Leichtman Capital Partners has acquired Genova Diagnostics Inc. (Asheville, NC). Genova (formerly named Great Smokies Diagnostic Laboratory) is a specialty clinical laboratory that specializes in testing related to chronic fatigue, gastrointestinal disorders and hormone imbalances. Genova was sold by private equity firms Nautic Partners LLC and Ferrer Freeman & Co. LLC. Genova's management, including CEO Ted Hull, has retained a stake in the company. Terms of the investment were not disclosed.

## MIRACA BUYS PLUS DIAGNOSTICS

Miraca Life Sciences Inc. has acquired Plus Diagnostics Inc. (Union, NJ) from Water Street Healthcare Partners for an undisclosed price.

Water Street acquired Plus in 2006 when it was a regional laboratory with approximately 50 employees named Lakewood Pathology. Over the past seven years, Plus has opened new labs in Irvine, California and Houston, Texas and expanded into the dermatopathology, hematopathology, and gastrointestinal markets. Plus currently has about 360 employees.

Miraca has now acquired three pathology lab companies—Aloha Labs, OncoDiagnostic Lab and Plus Diagnostics—since its $725 million purchase of Caris Diagnostics (Irving, TX) in November 2011.

## VIRACOR-IBT TO ACQUIRE NIT LAB

Viracor-IBT Laboratories (Lee's Summit, MO) has agreed to buy the laboratory operations of the National Institute of Transplantation. This includes the acquisition of NIT's Los Angeles-based lab operations, which perform serology testing on donor blood to determine the acceptability of a donor's organs and tissue to suitable recipients. NIT's expertise in pre-transplant testing is expected to complement Viracor-IBT's existing capabilities in post-transplant diagnostics.

# VERACYTE RAISES $58 MILLION FROM IPO

Veracyte Inc. (South San Francisco, CA) raised net proceeds of $58 million through an initial public offering (IPO) completed on October 30. Veracyte sold 500,000 shares of common stock at $13 per share. Morgan Stanley and Leerink Swann were lead managers of the IPO. William Blair and Cowen and Company acted as co-managers.

Veracyte plans to use the IPO proceeds to expand its sales force and develop new tests.

Veracyte has developed a proprietary thyroid test that is marketed under the brand name Afirma Thyroid FNA. The test is aimed at the 15% to 30% of roughly 525,000 fine needle aspirations (FNAs) annually where labs can't determine whether a thyroid nodule is cancerous or benign. Veracyte began marketing the test, which has a list price of $4,275, in January 2011. Medicare covers the test, as well as UnitedHealthcare, Aetna and Humana. Veracyte says Afirma can help patients avoid unnecessary surgery for the removal of their thyroid glands, which costs about $15,000 and may require hormone replacement therapy.

Physician clients send their thyroid nodule FNA samples to Veracyte's collection facility in Austin, Texas. Here a cytopathology specialist from Thyroid Cytology Partners (TCP) performs an assessment of the FNA sample under the microscope. TCP is an independent thyroid-only cytopathology group that is contracted with Veracyte. If TCP's cytopathology diagnosis is benign or malignant, the analysis is complete. But if the cytopathology diagnosis is inconclusive (TCP's indeterminate rate is approximately 14% to 17%), then a separate sample is sent to Veracyte's CLIA-certified laboratory in South San Francisco where the Afirma test is performed.

Veracyte markets Afirma through its own sales force. In addition, Genzyme's endocrinology sales team markets the test through a co-promotion agreement.

Veracyte reported a net loss of $13.4 million for the six months ended June 30, 2013; revenue increased 139.5% to $9.5 million. Veracyte received 23,181 FNAs in first-half 2013, up 142.3% from 9,535 in the same period last year. As of June 30, 2013, Veracyte had an accumulated deficit of $73.5 million.

In the second quarter of 2014, Veracyte plans to introduce its second test, Afirma Malignant GEC, which is intended to guide surgical strategy for the treatment of medullary thyroid cancer and other rare and metastatic forms of thyroid cancer.

Veracyte's largest shareholders include the venture capital firms: Versant Ventures, 17.2% stake; TPG Biotechnology Partners, 16.9%; KPCB Holdings, 16.9%; and Domain Partners, 14.7%. Veracyte's Chief Executive Bonnie Anderson owns 806,000 shares, or a 3.5% stake, with a current value of approximately $10.5 million.

### Veracyte at a Glance ($000)

| | | | *Six months to June 30* |
|---|---|---|---|
| | ***2013*** | ***2012*** | ***% Chg*** |
| Revenue | $9,452 | $3,947 | 139.5% |
| Net loss | -13,385 | -8,874 | NA |
| FNAs received | 23,181 | 9,535 | 143.2% |

Source: Veracyte Inc.

# COMPARING PRODUCTIVITY AT QUEST, LABCORP AND BRLI

On a weighted basis, three publicly traded lab companies collected average revenue of $45.54 per requisition in 2013, based on annualized results for the first three quarters. Average collected revenue per test is an estimated $15.18.

The three companies—Quest Diagnostics, LabCorp and BioReference Labs Inc. (BRLI)—have generated an average of $172,912 in revenue per employee this year. The average number of requisitions processed is 3,642 per employee per year, while employees processed an average of 10,927 tests per year. These figures are based on the total number of employees at the three companies, including all administrative, couriers, sales and marketing, and lab technical staff.

In terms of billing and collection, the average bad-debt expense for the big three commercial labs is 4.2% with an average days in accounts receivables of 52 days.

The combined revenue mix at the three publicly-traded labs is approximately 49% from commercial insurance, 26% client bill, 18% Medicare, 6% patient bill and 1% from Medicaid.

## Productivity Stats at Quest, LabCorp and BioReference Labs*

| | *Quest Diagnostics* | *LabCorp* | *BioReference* | *Totals*** |
|---|---|---|---|---|
| Annual Revenue 2013 | $7,186,036,000 | $5,828,400,000 | $697,514,667 | $13,711,950,667 |
| Annual Pretax Income 2013 | $1,480,416,000 | $1,282,489,333 | $81,765,333 | $2,844,670,667 |
| # Employees | 41,500 | 34,500 | 3,300 | 79,300 |
| | | | | |
| Avg. Revenue per Employee | $173,157 | $168,939 | $211,368 | $172,912 |
| Avg. Pretax Income per Employee | $35,673 | $37,174 | $24,777 | $35,872 |
| | | | | |
| Annual Requisitions 2013 | 149,500,000 | 131,066,667 | 8,265,333 | 288,832,000 |
| Avg. Revenue per Requisition | $44.33 | $44.49 | $83.83 | $45.54 |
| Avg. Reqs processed per Employee | 3,602 | 3,799 | 2,505 | 3,642 |
| | | | | |
| Annual Tests (assumes 3 tests per req.) | 448,500,000 | 393,200,000 | 24,796,000 | 866,496,000 |
| Avg. Revenue per Test | $14.78 | $14.83 | $27.94 | $15.18 |
| Avg. Tests processed per Employee | 10,807 | 11,397 | 7,514 | 10,927 |
| | | | | |
| Bad-Debt Expense | $272,133,333 | $250,621,200 | $57,836,000 | $580,590,533 |
| Bad-Debt % | 3.8% | 4.3% | 8.3% | 4.2% |
| Days in AR | 48 | 50 | 95 | 52 |

*Based on annualized results for the first 3 quarters of 2013
**Averages are weighted based on size
Source: *Laboratory Economics* from company reports

## LAB STOCKS UP 9% YTD

Fourteen lab stocks are, on average, up 9% in price year to date through November 19. In comparison, the S&P 500 Index is up 28%. The top-performing lab stocks so far this year are NeoGenomics, up 50%, and Foundation Medicine, up 34%, followed by Cancer Genetics, up 33%. Quest Diagnostics is up 6% and LabCorp is up 20%.

| Company (ticker) | Stock Price 11/19/13 | Stock Price 12/31/12 | 2013 Price Change | Market Capitalization ($ millions) | P/E Ratio | Price/ Sales | Price/ Book |
|---|---|---|---|---|---|---|---|
| Bio-Reference (BRLI) | $35.86 | $28.63 | 25% | $994 | 21.0 | 1.4 | 3.8 |
| Cancer Genetics Inc. (CGIX) | 13.28 | 10.00 | 33% | 123 | NA | 21.1 | 25.1 |
| CombiMatrix (CBMX) | 2.37 | 5.28 | -55% | 11 | NA | 1.8 | 2.5 |
| Enzo Biochem (ENZ) | 2.39 | 2.70 | -11% | 98 | NA | 1.0 | 2.8 |
| Foundation Medicine (FMI) | 24.10 | 18.00 | 34% | 678 | NA | 29.3 | NA |
| Genomic Health (GHDX) | 35.26 | 27.24 | 29% | 1,084 | NA | 4.2 | 7.8 |
| LabCorp (LH) | 103.96 | 86.62 | 20% | 9,086 | 16.3 | 1.7 | 3.6 |
| LipoScience (LPDX) | 4.02 | 9.00 | -55% | 61 | NA | 1.2 | 1.3 |
| Myriad Genetics (MYGN) | 27.59 | 27.25 | 1% | 2,062 | 13.2 | 3.3 | 3.1 |
| NeoGenomics (NEO) | 3.72 | 2.48 | 50% | 182 | 124.0 | 2.8 | 9.0 |
| Psychemedics (PMD) | 13.42 | 10.75 | 25% | 71 | 21.9 | 2.7 | 5.9 |
| Quest Diagnostics (DGX) | 61.52 | 58.27 | 6% | 9,000 | 12.7 | 1.3 | 2.1 |
| Response Genetics (RGDX) | 1.39 | 1.39 | 0% | 48 | NA | 2.3 | 12.3 |
| Sonic Healthcare (SHL.AU) | 16.38 | 13.33 | 23% | 6,560 | 19.2 | 1.9 | 2.2 |
| Unweighted Averages | | | 9% | | 34.9 | 6.0 | 6.1 |

Source: Zacks