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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

Top 10 Unintended Consequences If PAMA Rate Cuts Are Finalized

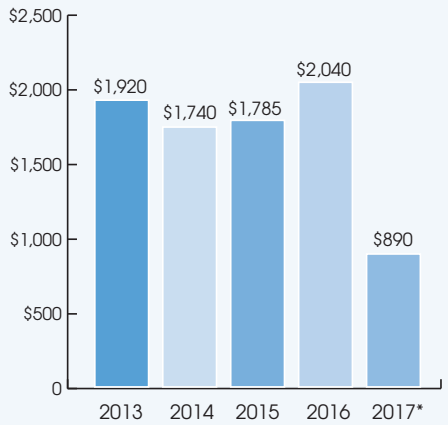
Assuming the proposed rates are finalized (see separate *LE* bulletin), CMS expects its new market-based reimbursement system for clinical lab tests to save the Medicare program approximately $4 billion over the next 10 years. But the new pricing system will result in numerous unintended consequences that are likely to dramatically reduce its projected savings. For *Laboratory Economics*' Top 10 List of Unintended Consequences, see page 5.

C21 Members To Get Rate Hikes Under Proposed CLFS For 2018

The prospect of three straight years of 10% rate cuts for most lab tests on Medicare's CLFS has the clinical laboratory industry sweating bullets and pushing for a delay in implementation. Meanwhile, The Coalition for 21st Century Medicine (C21-Arlington, VA), which is comprised of a small group of genetic testing labs and their private equity investors, is applauding the move to market-based rates and lobbying CMS to stay on schedule. That's because Medicare reimbursement rates for many of the high-priced proprietary tests offered by C21 lab members are set to increase in 2018.

Under the preliminary CLFS rates issued by CMS, for example, reimbursement for a routine lipid panel (CPT 80061) will be slashed by 39% to $11.23, while the rate for the Oncotype DX Breast Cancer Test (CPT 81519) offered exclusively by C21 member Genomic Health Inc. will rise by 12% to $3,873.

Lobby Spending by C21 and its Members ($000)



*Through August 7, 2017.

Source: Center for Responsive Politics (OpenSecrets.org)

Over the past five years, C21 and its members have spent a combined total of more than $8 million on lobbying Congress, FDA and CMS primarily for three key issues: 1) urging CMS to link Medicare rates for lab tests to private-payer rates; 2) limiting FDA regulation of laboratory-developed tests; and 3) avoiding bundled payment for molecular tests performed on hospital outpatients. It looks like C21's lobbying efforts have paid off on all counts, observes *Laboratory Economics*.

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At Press Time!!!

Laboratory Economics has learned that the "Big 3" national labs—Quest Diagnostics, LabCorp and Opko's Bio-Reference Labs—are making plans to file a lawsuit in the event that the lab industry's grassroots and lobbying efforts fail to persuade CMS to delay moving forward with its flawed market-based CLFS rates for 2018.

Any potential lawsuit would likely seek an injunction to stop CMS from finalizing the 2018 CLFS, so that a more representative sample of the lab market can be included in the agency's pricing calculations.

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C21 Members To Get Rate Hikes (*cont'd from page 1*)

Among the biggest members of C21 are the publicly-traded genetic and molecular testing lab companies Myriad Genetics, Foundation Medicine, Genomic Health, CareDx and Veracyte. C21 also includes more than a dozen privately held genetic testing labs, including Biodesix, Castle Biosciences, Helomics and Sera Prognostics. And finally C21 includes two private equity firms—Domain Associates and Kleiner Perkins Caufield & Byers—that have significant investment stakes in genetic and molecular testing lab companies.

Lobby Spending by C21 and its Members ($000)

	2017*	2016	2015	2014	2013
21st Century Medicine	$320,000	$790,000	$760,000	$660,000	$830,000
Biodesix	60,000	120,000	135,000	100,000	120,000
CareDx	20,000	20,000	40,000	0	0
Foundation Medicine	100,000	160,000	170,000	0	0
Genomic Health	0	10,000	80,000	330,000	440,000
Myriad Genetics	330,000	820,000	600,000	650,000	530,000
Veracyte	60,000	120,000	0	0	0
Grand Total	$890,000	$2,040,000	$1,785,000	$1,740,000	$1,920,000

*Through August 7, 2017.

Source: Center for Responsive Politics (OpenSecrets.org)

C21 was originally formed in 2006 to address the FDA's proposed regulation of laboratory-developed tests. Then in 2014, C21 was a prominent advocate for the passage of the Protecting Access to Medicare Act (PAMA) Section 216 that linked Medicare reimbursement for lab tests to private-payer rates.

Unlike the rest of the lab industry, C21 and its members have supported the PAMA repricing because Medicare reimbursement for many high-priced proprietary genetic and molecular tests is below the rates paid by private insurance companies. The end of generic code stacking and the creation of specific CPT codes and Medicare payment rates for genetic and molecular tests in 2013-2014 had resulted in drastic cuts.

The cuts pushed Medicare payment rates for many genetic and molecular tests below those paid by private insurance companies.

Now under the new PAMA method of setting lab test reimbursement based on weighted median private-payer rates, those labs that market proprietary genetic and molecular tests seem to be gaining an almost monopoly-like power to price their tests, especially for new tests.

Existing Proprietary Genetic and Molecular Tests

Examples of proprietary genetic and molecular tests that will receive big Medicare rate hikes next year include Myriad Genetics' Vectra DA (CPT 81490), which is increasing 42% to $840.65. Vectra DA measures the levels of 12 protein biomarkers related to rheumatoid arthritis.

In addition, the primary billing code (CPT 81211) for Myriad's flagship BRACAnalysis test, which assesses a woman's risk for breast and ovarian cancer, is being raised by 9% to $2,395.84. A handful of other labs offer competing tests that analyze BRCA1 & BRCA2 genes at substantially

lower prices. However, Myriad's test still has by far the lion's share of the market and therefore its private-payer rates had the greatest influence in setting Medicare's preliminary rate for 2018.

Other examples include Veracyte's Afirma Gene Expression Classifier (CPT 81545), which is being increased by 12% to $3,600; CareDx's AlloMap (CPT 81595), up 14% to $3,240; and Biotheranostics' CancerType ID (CPT 81540), up 28% to $3,750.

Sample of Preliminary 2018 Medicare Payment Rates for Proprietary Tests

Code	Test Name	Laboratory Company	Short Test Description	Medicare 2017 NLA	CMS Preliminary 2018 Rate	Percent Change
81211	BRACAnalysis	Myriad Genetics	BRCA 1&2 sequence analysis & com duplication/deletion	$2,195.48	$2,395.84	9.1%
81490	Vectra DA	Myriad Genetics	Autoimmune rheumatoid arthritis analysis of 12 biomarkers	590.61	840.65	42.3%
81493	Corus CAD	CardioDx	Coronary artery disease mRNA gene expression profiling	1,042.35	1,050.00	0.7%
81519	Oncotype DX Breast Cancer Assay	Genomic Health	Oncology breast mRNA	3,443.36	3,873.00	12.5%
81535	ChemoFX	Helomics	Oncology gynecologic	583.52	579.46	-0.7%
81538	VeriStrat	Biodesix	Oncology lung	2,126.78	2,871.00	35.0%
81540	CancerType ID	Biotheranostics	Oncology tumor of unknown origin	2,920.30	3,750.00	28.4%
81545	Afirma Gene Expression Classifier	Veracyte	Oncology (thyroid), gene expression analysis	3,222.40	3,600.00	11.7%
81595	AlloMap	CareDx	Cardiology heart transplant mRNA	2,840.75	3,240.00	14.1%

Source: Laboratory Economics from C21 and CMS

New Proprietary Genetic and Molecular Tests

Importantly, PAMA created a special separate category for new proprietary tests called Advanced Diagnostic Laboratory Tests (ADLTs). PAMA defines an ADLT as a test that is furnished only by a single laboratory and meets one of the following criteria: (A) The test is an analysis of multiple biomarkers of DNA, RNA, or proteins combined with a unique algorithm to yield a single patient-specific result; (B) The test is cleared or approved by the FDA; or (C) The test meets other similar criteria established by CMS.

CMS is requiring laboratories to submit documentation to support their application for ADLT status, including evidence of their empirically derived algorithms and how their test provides new clinical diagnostic information that cannot be obtained from any other test or combination of tests.

ADLT Pricing

Most importantly, CMS seems to be giving labs that develop ADLTs carte blanche to set their own pricing. For a new ADLT, the Medicare rate for the first nine months will be the "list charge" set by the offering laboratory when the test becomes available for purchase by a private payer. After the initial nine months, the Medicare rate will be set at the weighted median of reported private-payer rates. Private payers have always had difficulty understanding and pricing new genetic and molecular tests.

Under the new rate setting method, lab companies introducing new ADLTs could game the system by setting high initial list prices and then driving volume toward the best, or most ignorant, private payers for the first nine months. Medicare would then set their rate based on this skewed information.

In a press release that followed CMS's release of the preliminary 2018 CLFS rates, C21 commended the agency and said it "supports the implementation of the PAMA market-based rates on January 1, 2018….C21 also urges CMS to finalize a streamlined process for designating advanced diagnostic laboratory tests (ADLTs) which will serve as a catalyst for innovative genomic diagnostics that benefit patients by personalizing medical treatment decisions."

If the rate increases for existing proprietary tests are finalized and the special method for pricing ADLTs goes into effect, the field of genetic and molecular testing is going to start looking even more like the pharmaceutical industry than it already does, predicts *Laboratory Economics*. That is, proprietary and patented expensive products with government price protection being sold to prescribing doctors by an army of sales reps and marketed to consumers directly through TV and internet advertising.

Q&A With NILA's Mark Birenbaum

The National Independent Laboratory Association (NILA-St. Louis, MO), which represents approximately 100 independent labs across the country, has been opposed to linking the Medicare CLFS to private-payer rates since the idea first began getting traction in late 2013. *Laboratory Economics* recently spoke with NILA Administrator Mark Birenbaum, PhD.

What's the biggest misunderstanding the lab industry has about the upcoming potential Medicare rate cuts?
That the proposed cuts will be limited to Medicare rates and will only badly hurt nursing home labs and other labs with a high percentage of Medicare revenue. If finalized, the Medicare rate cuts will ripple through to other payers that base their reimbursement as a percentage of the CLFS, including Medicaid fee-for-service plans and many private insurance companies. For most labs, the Medicare rate cuts could wind up affecting 50% or more of their revenue.

What is NILA's strategy for trying to stop the rate cuts from being finalized and implemented?
We are urging labs and their employees to call their U.S. Representatives and Senators to insist that Congress intervene and stop CMS from moving forward so that all labs can be represented in the pricing calculations. Grassroots efforts like this have been successful in the past. For example, in repealing a CMS requirement for physician signatures on all Part B clinical laboratory requisitions in 2011, and in blocking CMS's competitive bidding demonstration project for CLFS payments in 2007.

What about filing a lawsuit to stop CMS from proceeding with the rate cuts?
It's a possibility, but there are certain obstacles that could hinder a successful legal challenge, including a section of the PAMA law that states, "There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, of the establishment of payment amounts under this section." The government will argue that its rates can't be challenged.

What about the role of C21 and its members?
A handful of proprietary lab companies are urging CMS to finalize the rates on schedule effective January 1, because their already-expensive tests will get rate increases and they'll get a blank check for pricing new tests. It's sending a confusing message to Washington because a handful of labs are lobbying in favor of the new payment system, while the overwhelming majority of labs is asking for a delay and fix.

Top 10 Unintended Consequences From PAMA Rate Cuts (*cont'd from p. 1*)

CMS is counting on billions of dollars of savings as a result of the switch to market-based pricing for clinical lab tests, but there will be numerous costly unintended consequences that will dig into projected savings.

1. Increased Spending on High-Priced Proprietary Esoteric Tests

By slashing rates for routine testing and increasing rates for the highest-priced esoteric tests, CMS is creating an environment that will force many independent routine testing labs out of business. At the same time, proprietary labs marketing esoteric tests with prices that range between $500 and $4,000 per test will flourish. Private equity investors can be expected to pour hundreds of millions of dollars into funding new esoteric labs to take advantage of the special pricing rules for advanced diagnostic laboratory tests (ADLTs). "It appears that the foxes are being given watch over the hen house," an executive from a Medicare Administrative Contractor tells *Laboratory Economics*.

2. Medicare Rate Changes will have a Ripple Effect

What is the correct way to fairly price each of the 1,000+ lab test codes on the Clinical Laboratory Fee Schedule? Nobody really knows. Commercial insurance companies have historically fixed their lab test reimbursement rates to a percentage of Medicare. Now Medicare is setting its rates based on commercial rates, thereby creating the potential for an unending cycle of price reductions from all payers.

Many labs have sought to insulate themselves from this vicious circle by locking in their current commercial payer rates to long-term contracts of five years or more. But *Laboratory Economics*' off-the-record interviews with executives at several independent labs suggest there is no way to completely stop the ripple effect.

For example, there's no way to stop Medicaid fee-for-service rates, which generally are a fixed discount to the Medicare CLFS, from being lowered at the start of their new fiscal years. "It's really wishful thinking to think that commercial payers won't hammer down rates as contracts come up for renewal. Even Quest and LabCorp don't have the leverage you think they do," says Tom Hirsch, President of Laboratory Billing Solutions (Portsmouth, NH). "Hospital labs have had much greater success in negotiating reasonable commercial contracts, whether as a percentage of billed charges or the Medicare lab fee schedule."

3. More Labs Going Out-of-Network

Commercial rates have the potential to go so low that it may make sense to go out-of-network for some contracts. Labs will need to weigh the potential loss of volume versus the higher payment they can receive as a non-participating laboratory for each of their contracts. Out-of-network providers must also collect higher co-pay percentages and deductibles directly from patients.

4. Lab Test Prices for Direct-Paying Customers will Increase

There's only one place where labs have the ability to raise prices for routine lab tests, and that's for people with no health insurance who pay out-of-pocket. For the past 20 years, prices charged to self-paying patients have continuously been raised to offset pricing pressure from Medicare, Medicaid and commercial insurance plans. The "rack rates" that Quest Diagnostics and LabCorp bill self-paying patients are often as much as 10 times more than current Medicare rates, and hospital labs generally charge even more. A big hike in rack rates can be expected if the Medicare cuts are finalized for 2018.

5. Pressure on Reagent Rental Contract Prices

Pricing pressure will trickle down to reagent prices, says Steven Boyd. He founded Southern

Diagnostic Laboratories (Birmingham, AL) in 2003, sold it to Solstas Lab Partners in 2011, then helped found a new independent lab company, Southeast Clinical Laboratories (Gadsen, AL) in late 2014. "Every five to seven years, there's some catastrophic change to the lab industry, either involving new coding requirements or pricing. It's survivable. We'll find ways to be more efficient."

6. Pressure on Send-Out Test Prices

Hospital labs and independent labs spend more than $5 billion annually for send-out tests supplied primarily by four national reference lab companies: ARUP Laboratories, LabCorp, Mayo Medical Laboratories and Quest Diagnostics. Lower reimbursement rates for routine tests and the resulting budget pressure will push labs to lower their utilization and seek greater discounts for their send-out tests.

7. The Nursing Home Lab Market will Collapse

The provision of lab testing services to nursing homes and homebound patients is a low-margin business that is served primarily by small independent labs and local hospital labs. Independent labs serving this market often receive 50% to 90% of their revenue from Medicare and Medicaid. CMS tried to soften the blow of the coming rate cuts by raising the sample collection fee (G0471) for nursing home and homebound patients by $2, from $3 to $5, effective April 1, 2014. However, it's not nearly enough to offset three years in a row of 10% rate cuts to the majority of their business. Dozens of small independent labs across the country will be forced out of business as a result.

8. The Toxicology Lab Market will Collapse

Medicare reimbursement for the drugs-of-abuse testing codes was reduced by roughly 75% by new bundling G-codes that became effective in 2016. The 75% cut slowly rippled through to commercial insurance reimbursement rates throughout 2016, putting many pain-medication-monitoring labs out of business, according to Lale White, Chief Executive of XIFIN Inc. (San Diego, CA). The proposed market-based rates for the G-codes will mean additional cuts of 40% to 60% phased-in over the next three to five years. For example, G0480 (drug test definitive, 1-7 classes) is proposed to be cut by a total of 59%, subject to a maximum 10% annual reduction for the first three years of implementation (2018-2020), followed by an annual cap of -15% from 2021-2023. Not many toxicology labs, which are already buckling from the 2016 cuts, will be able to survive the proposed further reductions starting in 2018.

9. Geographically: States with High Medicare Populations will be Hurt the Most

Obviously, labs located in states with a high percentage Medicare population will be disproportionately hurt by the proposed rate cuts. The top five are West Virginia (19% Medicare population), Florida (18%), Maine (18%), Montana (17%) and Arkansas (16%). In addition, labs in states with high Medicaid populations will be hurt as price reductions ripple through to Medicaid fee-for-service rates. The top five are West Virginia (29% Medicaid population), New Mexico (27%), California (26%), Arizona (25%) and New York (25%).

10. Codes with No NLA will get Slammed Immediately

As it stands now, a handful of CPT codes that do not have a Medicare National Limit Amount (NLA) will be priced at their median private-payer rate immediately effective January 1, 2018. Reduction limits can't be phased-in because there is no NLA. The most important of these is the lipid panel (CPT 80061) which has a proposed rate of $11.23, which is equivalent to 39% less than the $18.37 that most Medicare contractors currently pay. This means that labs specializing in cardiovascular health and lipid testing may feel the full brunt of a Medicare price reduction in 2018, with no phased-in cap on reductions.

The Outlook For Hospital Lab Outreach Testing

What happens to hospital lab outreach programs if the proposed Medicare CLFS rate cuts are finalized? For answers, *Laboratory Economics* spoke with Jeff Myers, Vice President for Consulting with Accumen Inc. (San Diego), which recently published results from its Chi Solutions 16th Annual National Hospital Laboratory Outreach Survey.

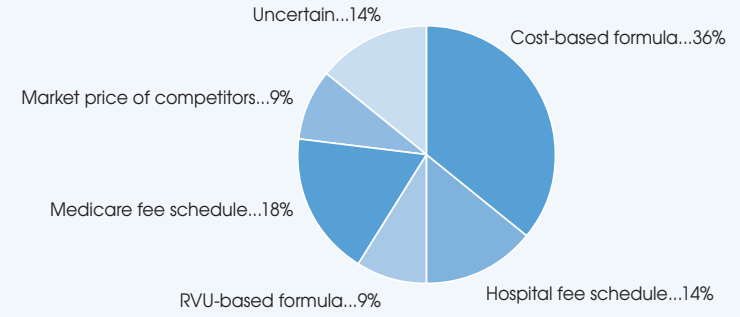
Jeff Myers

How damaging will the proposed Medicare rate cuts be to hospital outreach labs?
The typical hospital outreach lab gets 25% to 30% of its revenue from the Medicare CLFS, so the proposed 10% reduction in 2018 Medicare rates would translate to a 2.5% to 3% revenue loss. However, most hospital outreach labs are insulated from the cuts rippling through to their private-payer rates because these rates are negotiated as part of their hospital's overall outpatient contracts and are not tied to the CLFS. Hospital outreach lab rates are often two to three times more than what the commercial labs are paid.

But the higher reimbursement for hospital labs has become a double-edged sword. With increasing deductibles and co-pays, more and more financial burden has shifted to patients. Patient concerns and awareness about hospital pricing are at an all-time high. The national laboratories as well as many private insurers have marketing campaigns to steer business away from hospitals because of pricing.

Physicians are sensitive to the out-of-pocket costs of their patients. So more physicians, even those employed by health systems with outreach labs, are facing increased pressure to send their patients to lower-priced labs.

Hospital Lab Outreach Price Determination



Source: Accumen Inc. and Chi Solutions Inc. Hospital Laboratory Outreach Survey 2017

Many of the larger, more sophisticated lab outreach programs have shifted to Medicare CLFS rates to remain competitive and maintain market share.

What are the biggest cost reduction opportunities at hospital labs?
There are more than enough cost reduction opportunities present at hospital labs to offset the potential Medicare rate reductions. Many health systems are addressing reimbursement declines with a cost improvement plan in the clinical laboratory, which includes analyzing cost improvement opportunities, creating a cost improvement plan, and finally executing the cost improvement plan.

Employee salary and benefits are the biggest component of operating expenses, comprising an average of about 55% of the typical hospital lab department budget. There is room to optimize staffing levels at most hospital labs by tying work schedules to volume levels, test consolidation, and productivity and process improvements.

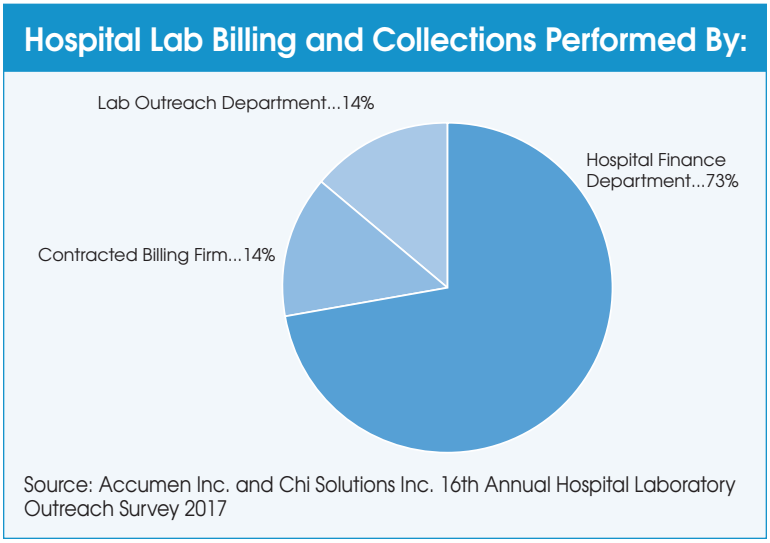
Reagents and supplies are an average of about 25% of the budget, and there will be pressure to lower reagent rental contract prices, better control inventory management, test utilization, and more standardization of vendors.

Send-out testing averages about 12% of the budget. Many hospitals are using 15 to 20 different reference labs, so there is an opportunity to consolidate vendors and lower pricing.

Finally, everyone is talking about test utilization management, but the concept has not been put into widespread practice at hospital labs.

Why have some hospital outreach lab programs been sold to commercial labs?
A handful of outreach lab businesses have been sold over the past few years. The commercial labs depend on acquisitions for growth and, in general, hospital CEOs and CFOs don't have a good understanding of how much revenue their lab outreach testing is producing. But they do see the costs, so that's their focus.

Because most hospitals commingle their outpatient and outreach testing and bill through the main hospital billing department, a separate financial statement for lab outreach is generally not available. So some outreach labs have been sold to lower costs, without an understanding of the associated loss in revenue.



Why haven't more hospital lab outreach programs taken control of their billing?
Only 14% of outreach labs perform their own billing and collection, while another 14% contract with an outside billing firm. That's because the majority of hospital outreach programs are treated as an extension of hospital outpatient laboratory services and combined with outpatient revenue. They have chosen to keep revenue cycle activities within the hospital finance department and not create a separate lab outreach department for billing.

Spotlight Interview With Wisconsin Diagnostic Lab's COO Steve Serota

Wisconsin Diagnostic Laboratories (WDL), formerly United/Dynacare Laboratories, serves more than 30 hospitals, 500 long-term care facilities and 100 outreach practices in Wisconsin and the Chicago area. The laboratory is the sole provider for Froedtert and the Medical College of Wisconsin and a reference lab for two other hospitals within the Froedtert Health System. WDL has about 500 employees. *Laboratory Economics* recently spoke with Chief Operating Officer, Steve Serota.


Steve Serota

Why did WDL end its joint venture agreement with LabCorp in 2015?
Froedtert wished to take a more introspective look at laboratory testing and to ensure that it was fully aligned with the health system's goals. During the course of the dissolution, WDL maintained laboratory testing for the Froedtert Health System. LabCorp secured the independent physician outreach business. A two-year non-compete agreement recently ended, and we are now back in the outreach market. Since July 2017 we've on-boarded 12 physician practices, and have a pipeline of about 48 more that are looking to utilize our services by the end of the year.

How is it competing with LabCorp for that business?
We are a local laboratory, which gives us the opportunity to be operationally efficient when it comes to logistical coordination. We are a leader in turnaround time, not only in commoditized testing but also esoteric testing. Being an academically affiliated medical laboratory with access to subspecialty pathology, we are able to offer nationally recognized pathology services and a comprehensive test compendium with everything from chemistry and hematology to flow cytometry and cytogenetics, as well as molecular diagnostics. Through a partnership with the Medical College of Wisconsin, we also offer genomic testing and dermatopathology, which makes us a one-stop shop.

Our approach to utilization management also drives value. We want to make sure the patient is getting the right test, at the right time, for the right reason, regardless of reimbursement. As we drive down testing to an optimal level for Froedtert's inpatients, we allow ourselves a reservoir of capacity that we can then fill with external and outreach work. We predict growth by another 40% with our existing infrastructure alone.

How much has test volume and revenue grown in the past couple of years?
Prior to dissolution of the joint venture, we were running a steady 5% growth rate. During the two-year non-compete period, we saw about a 2% growth rate driven by Froedtert's growth. In the coming year, we are estimating a 5% to 8% growth rate.

In what areas are you seeing the greatest amount of growth?
We've seen substantial growth in flow cytometry, microbiology/molecular diagnostics, and throughout our comprehensive subspecialty testing. Chemistry and hematology has seen predictable growth. We are seeing some growth in molecular genomics, but as the specialty evolves, we are concentrating on utilization management to ensure our patients receive clinically optimal testing. We also are experiencing growth in highly specialized lab-developed tests (LDTs). We currently perform well over 80 LDTs.

Have you calculated the impact of upcoming Medicare cuts to laboratory testing on WDL?
Given our ability to leverage existing infrastructure, we believe we'll be able to offset Medicare cuts through improved efficiency and incremental growth in our outreach business.

With the move toward payment models tied to value or outcomes, is WDL doing anything to add additional value to clients beyond just providing test results?
Data analytics is the next major domain in laboratory medicine and we are continuing to walk that path. We also are working with our Froedtert Health partners to move laboratory medicine closer to the bedside; one example of this is interdisciplinary rounding to ensure that clinical expertise of WDL's pathologists are available to patients and physicians.

What do you see as the greatest opportunities for WDL?
We have a tremendous opportunity to grow locally, to offer a differentiated value proposition to more of our local and regional community. We also act as a forward-leaning arm of Froedtert Health System, so we are in a good position to go out and work with independent providers and large and small health systems to really make sure that laboratory medicine is driving maximum value to clinicians and patients.

What are your biggest challenges?
Our biggest challenge is understanding and moving away from the current transactional nature of laboratory medicine to a model where clinical utility and value are placed ahead of profits.

Quest To Buy Shiel Medical Laboratory in Brooklyn

Quest Diagnostics is buying the assets of Shiel Medical Laboratory (Brooklyn, NY) from Fresenius Medical for an undisclosed amount. Shiel was acquired by Fresenius, which operates more than 2,000 dialysis clinics in the United States, in October 2013. The sale to Quest is expected to close by December 31.

Shiel employs more than 630 employees, operating in a 50,000-square-foot laboratory facility in Brooklyn as well as approximately 25 patient service centers in the New York City region. Shiel's annual revenue is estimated to be between $75 million and $100 million, including more than 35% from Medicare Part B payments.

Quest plans to close Shiel's Brooklyn lab and shift testing to its regional laboratory in Teterboro, New Jersey. Some 538 Shiel employees are expected to lose their jobs, although some may be rehired by Quest.

Fresenius said that Shiel is being sold because its growth failed to meet expectations and so that it can focus on its core dialysis business.

In addition, Fresenius says that its dialysis-related lab testing business, Spectra Laboratories (Rockleigh, NJ), will not be affected by the divestiture of Shiel.

Shiel Under Investigation

Separately, *Laboratory Economics* notes that a large portion of Shiel's business is lab testing for nursing homes and home care agencies. In November 2016, Fresenius received a subpoena from the United States Attorney for the Eastern District of New York seeking documents and information relating to the operations of Shiel Medical Laboratory.

In the course of responding to the subpoena, Fresenius says that it identified false documents submitted by a Shiel salesperson that relate to the integrity of certain invoices submitted by Shiel for lab testing provided to nursing home patients. In February 2017, Fresenius says that it fired the employee and notified the United States Attorney of the termination and its circumstances. In its 2016 annual report issued in early 2017, Fresenius said, "It cannot at this time determine the scope of the conduct implicated in the employee's termination, or whether related liability for overpayments or penalties under the False Claims Act might be material."

Quest's asset purchase agreement for Shiel is presumed to exclude any potential liabilities resulting from the U.S. Attorney's investigation, observes *Laboratory Economics*.

Quest Finalizes Purchase of Outreach Labs in Connecticut

In separate news, Quest says it has completed its acquisition of the outreach lab services operations of two Hartford HealthCare hospitals: William W. Backus Hospital and the Hospital of Central Connecticut.

Outreach tests performed at the two hospitals will now be processed at Quest's regional lab in Marlborough, Massachusetts.

This small deal follows Quest's $135 million acquisition of the outreach laboratory service business of Clinical Laboratory Partners (Newington, CT) in early 2016, which had been a wholly-owned subsidiary of Hartford HealthCare.

Avista Capital Partners To Buy Miraca Life Sciences

Private equity firm Avista Capital Partners (New York City) has agreed to acquire Miraca Life Sciences (MLS-Irving, TX) from Miraca Holdings (Tokyo, Japan) for an enterprise value of $175.6 million, including $135.4 million in cash plus the assumption of $40.2 million of lease obligations. Miraca Holdings will also keep a 15% stake in MLS. The deal values MLS at less than 1x its annual revenue. The transaction is expected to close in November.

Based in the Dallas area, MLS has approximately 1,100 employees including about 90 fellowship-trained subspecialist pathologists. The company operates four main labs across the country (Irving, Phoenix; Union, NJ; and Newton, MA) focused on gastropathology, dermatopathology, hematopathology, breast cancer and urologic pathology. MLS recorded an operating profit of $13 million on revenue of $266 million in the fiscal year ended March 31, 2017. Asset write-downs at MLS led to a $46 million loss attributable to parent Miraca Holdings in fiscal 2017.

Miraca Holdings had originally purchased Miraca Life Sciences (formerly named Caris Diagnostics) for $725 million in late 2011. However, the U.S. anatomic pathology market changed dramatically soon thereafter, including a major reimbursement cut to the technical component of CPT 88305 in 2013. "To realize further growth, a decision has been made that additional management resources and significant investment are required, such as for a hospital market entry and scale expansion," according to a press release from Miraca Holdings.

Avista Capital is a private equity firm with approximately $6 billion under management. It currently does not hold any investments in clinical or anatomic pathology labs. However, in the past Avista had held a stake in Prometheus Laboratories (San Diego), a specialty clinical lab now owned by Nestle Health Sciences. Avista had also held a stake in Focus Diagnostics (Cypress, CA), an IVD manufacturer specializing in immunodiagnostic and molecular diagnostic products that was sold to Quest Diagnostics in 2006. Quest subsequently sold Focus Diagnostics to Italy's DiaSorin in May 2016.

Miraca Life Sciences at a Glance ($ millions)

Fiscal year-end	*Mar-15*	*Mar-16*	*Mar-17*
Revenue	$258	$261	$266
Operating profit	-4	-1	13
Profit/loss attributable to Miraca Holdings	-16	-195	-46
Net assets	524	330	284
Total assets	831	656	535

Source: Miraca Holdings

Lab Stocks Up 48% YTD

Eighteen lab stocks have risen by an unweighted average of 48% year to date through October 16. In comparison, the S&P 500 Index is up 14%. The top-performing lab stocks so far this year are Exact Sciences, up 253%; CombiMatrix, up 196%; and Foundation Medicine, up 151%. At the two largest public labs, LabCorp is up 17% and Quest Diagnostics is unchanged.

Company (ticker)	Stock Price 10/16/17	Stock Price 12/31/16	2017 Price Change	Market Capitalization ($ millions)	P/E Ratio	Price/ Sales	Price/ Book
Cancer Genetics Inc. (CGIX)	$2.70	$1.35	100%	$65	NA	2.4	2.9
CareDx (CDNA)	5.78	2.70	114%	130	NA	2.8	10.5
CombiMatrix (CBMX)	7.85	2.65	196%	23	NA	1.6	3.9
Enzo Biochem (ENZ)	10.34	6.94	49%	481	15.2	4.5	5.4
Exact Sciences (EXAS)	47.20	13.36	253%	5,620	NA	33.2	10.4
Foundation Medicine (FMI)	44.40	17.70	151%	1,600	NA	13.4	17.8
Genomic Health (GHDX)	32.99	29.39	12%	1,140	NA	3.4	6.7
Interpace Diagnostics (IDXG)	1.48	4.40	-66%	33	NA	2.4	0.8
Invitae (NVTA)	9.84	7.94	24%	480	NA	12.0	6.4
LabCorp (LH)	149.67	128.38	17%	15,240	21.0	1.6	2.6
Myriad Genetics (MYGN)	36.10	16.67	117%	2,470	113.2	3.2	3.2
NeoGenomics (NEO)	9.52	8.57	11%	755	NA	3.0	4.5
Opko Health (OPK)	6.90	9.30	-26%	3,860	NA	3.3	1.8
Psychemedics (PMD)	17.15	24.99	-31%	94	12.7	2.2	5.7
Quest Diagnostics (DGX)	91.53	91.90	0%	12,490	18.5	1.7	2.7
Rosetta Genomics (ROSG)	1.00	5.04	-80%	3	NA	1.1	0.4
Sonic Healthcare (SHL.AX)	21.59	21.40	1%	9,070	21.2	1.8	2.4
Veracyte (VCYT)	9.04	7.74	17%	306	NA	4.3	6.4
Unweighted Averages			48%	$53,860	33.6	5.4	5.3

Source: Capital IQ

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