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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

FDA Plans to Finalize LDT Rule by April 2024

The Food and Drug Administration (FDA) plans to finalize its proposed rule on laboratory-developed tests by April 2024, according to a work plan published by the Office of Management and Budget (OMB). If the rule and related LDT policy are finalized by April 2024, high-risk LDTs will require premarket review as early as October 1, 2027. And low-to-moderate risk LDTs will require premarket review as early as April 1, 2028. A final rule is almost guaranteed to trigger a lawsuit(s) from lab trade groups, which will argue that the FDA does not have the authority to regulate LDTs.

FDA Regs Would Force Labs to Abandon Many LDTs

FDA regulation of laboratory-developed tests (LDTs), if finalized, will force academic medical centers, hospitals and independent labs to stop offering thousands of valuable tests. The cost of submitting a premarket approval (PMA) application to the FDA could easily exceed $1 million for each high-risk test, according to Jonathan Genzen, MD, PhD, Chief Medical Officer and Senior Director of Governmental Affairs at ARUP Laboratories (Salt Lake City, UT). "LDTs offered in low volume will become unaffordable in most settings," says Genzen.

More details on page 3.

Medicare CLFS Rates Might Be Frozen Indefinitely

Last month, both houses of Congress passed a stopgap bill that will delay scheduled rate cuts to the Medicare Clinical Laboratory Fee Schedule (CLFS) in 2024. As a result, CLFS rates will be frozen for the fourth straight year (2021-2024). It now looks like the CLFS is destined for repeated one-year rate freezes well into the future.

Details on page 8.

Sonic To Buy Pathology Watch for $130 Million

Sonic Healthcare has agreed to acquire Pathology Watch (Murray, UT) for $130 million (cash and debt free). Pathology Watch is a dermatopathology lab that has developed a digital software platform for skin pathology. The transaction is expected to close by the end of December.

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SONIC TO BUY PATHOLOGY WATCH FOR $130 MILLION (*cont'd from page 1*)
Pathology Watch has current annual revenue of $15 million per year but is unprofitable. Sonic's purchase price equates to a multiple of 8.7x revenue ($130M/$15M=8.7x).

Pathology Watch was founded in New York in 2017. Founders include former Chief Medical Officer Gregory Osmond, MD, Chief Executive Daniel Lambert and Chief Revenue Officer Michael Torno. The company relocated to Murray, Utah (just outside Salt Lake City) to lower costs and its laboratory was CLIA-certified in 2021.

Pathology Watch has 100 employees, including 16 board-certified dermatopathologists. Sonic plans to keep the Pathology Watch laboratory, staff and management intact.

Pathology Watch has developed an end-to-end system known as "DOT" (Dermatopathology Optimization Tool) which incorporates a laboratory information system, digital pathology viewer, image storage and AI algorithms.

Skin biopsies shipped to Pathology Watch are grossed, prepared on glass slides, and then scanned into digital images. The company's dermatopathologists interpret the digitized images. AI programs are run retrospectively for quality assurance. Most results are reported back to the ordering dermatologist within 48 hours of specimen pickup.

Pathology Watch is also developing an AI algorithm to predict the probability of metastases following a primary diagnosis of melanoma.

Pathology Watch has raised a total of more than $50 million from outside investors. Major investors include SpringTide Ventures, Rock Creek Capital and Ceros Financial Services.

Potential Synergies with Franklin.ai
Last year, Sonic Healthcare and artificial intelligence start-up Harrison.ai (Haymarket, Australia) formed a new joint venture (named Franklin.ai) to develop AI software tools for pathologists. Harrison.ai owns 51% of Franklin.ai, while Sonic owns 49%. Franklin.ai is nearing completion of its first AI product, with validation studies to begin in 2024. Sonic is hoping that Pathology Watch's end-to-end digital pathology platform can be used to speed the deployment of Franklin.ai's products into Sonic's anatomic pathology practices worldwide.

Sonic's Expanding AP Business
Sonic is one of the world's largest anatomic pathology providers with annual worldwide AP revenue of >$650 million and employing >1,200 pathologists, including roughly ~400 pathologists in the United States.

Sonic Healthcare's U.S. Anatomic Pathology Acquisitions ($ millions)

Date	AP Acquisition	Purchase Price	Annual Revenue	Price/ Revenue
Dec-23	Pathology Watch (Murray, UT)	$130	$15	8.7
Dec-21	Propath Services (Dallas, TX)	NA	$120	NA
Jan-19	Aurora Diagnostics (Palm Beach Gardens, FL)	$540	$310	1.7
Feb-12	Bridger Pathology Labs (Montgomery, AL)	NA	NA	NA
Feb-11	Central Coast Pathology Consultants (San Luis Obispo, CA)	NA	$20	NA
Dec-10	CBLPath (Rye Brook, NY)	$124	$85	1.5

Source: *Laboratory Economics*

FDA REGS WOULD FORCE LABS TO ABANDON MANY LDTS (*cont'd from page 1*)
ARUP Laboratories, a nonprofit enterprise of the University of Utah, is one of the biggest reference labs in the nation with more than 4,000 employees and annual revenue of roughly $800 million. The test menu at ARUP includes 3,000+ tests of which approximately 1,500 are LDTs. Here's a summary of our interview with Dr. Genzen:

What are the chances that the FDA publishes a Final Rule on LDTs?
I expect a final rule to be published as early as this spring. The FDA is moving quickly because the national election in November 2024 could result in a new administration with a different opinion on LDT regulation. There are really only three people who can stop the final rule from being published, the head of the FDA, the head of the Department of Health and Human Services, and the President.


Jonathan Genzen, MD, PhD

What are the estimated costs of getting a Medium-Risk and High-Risk LDT cleared by the FDA?
The direct cost of submitting a 510(k) application to the FDA is $21,760 per test. A de novo classification request for a medium-risk LDT with no predicate costs $145,068 per application. Importantly, the de novo classification and fees apply to FDA-cleared tests that labs have modified (e.g., different specimen type or temperature storage than on the label).

The FDA fee for a high-risk PMA submission is $483,560 per test plus an annual reporting fee of $16,925 per test.

But there are also personnel costs, which extend from the original validation activities, to work associated with preparing submission paperwork, as well as the costs for any repeat studies that the FDA may require.

Furthermore, since the quality standard requirements under CLIA are different than FDA processes, I anticipate that many laboratories may need to do a substantial amount of additional work to meet FDA format and review requirements, even though the tests are already validated under CLIA. There are also regulatory costs, such as annual fees for adverse event reporting systems, as well as additional quality staff to track reporting requirements over time. All of this will increase the cost of testing.

Adding all costs leads to an estimate of more than $1 million per high-risk test and several hundred thousand dollars per medium-risk LDT with no predicate. The incentive to create and pursue low-volume LDTs will be lost.

What should labs offering LDTs be doing right now?
Map out your LDT test menu with anticipated risk categorizations for each test. This can be subjective, but you need to start planning. Labs are going to need to begin looking at the medical utility and profitability/sustainability of each of their LDTs.

Current FDA User Fees

Application Type	*Standard Fee*	*Small Business Fee**
Medium-Risk 510(k)	$21,760	$5,440
Medium-Risk (No predicate) De Novo Classification Request	$145,068	$36,267
High-Risk PMA, PDP, PMR, BLA	$483,560	$120,890
Annual fee for periodic reporting on High-Risk Tests (PMAs, PDPs and PMRs)	$16,925	$4,231

*A small business is defined as a business, including its affiliates, whose gross receipts and sales are less than $100 million for the most recent tax year. Source: FDA

The Outlook for the Lab Industry, According to Gary Huff

Gary Huff has spent the last 30 years managing laboratories, including his experience as CEO of LabCorp Diagnostics as well as at Baylor Genetics Laboratories. Huff now heads his own Advisory firm Take Charge LLC (Wilmington, NC). He also serves on the boards at Lighthouse Lab Services and Accumen Inc. and serves as an M&A advisor for Advanced Strategic Partners. Here's a summary of *LE*'s broad ranging interview with Mr. Huff.

Gary Huff

What are key success strategies for smaller labs post-pandemic?
Post-pandemic inflation has been especially tough on smaller labs that don't have economies of scales to create as many options to cut costs as the national labs. As a result, intense control of costs is a must for small labs—pennies add up and are important, even when you are small.

Smaller labs must also focus on profitable volume growth—not all volume is good volume. Find your profitable niche, create differentiation, provide superior service, and pursue it relentlessly. For example, post pandemic many small labs expended time and energy looking to expand into different states when they hadn't maximized opportunity in their local geography. This proved to be extremely costly and caused them to get distracted and take their focus away from what initially made them successful.

What about for the larger labs?
One key will be their ability to leverage their vast databases of information with AI and machine learning. This includes collaborating and utilizing shared data with health plans and health systems. The challenges here are overcoming the data ownership hurdle and managing inconsistent data from multiple sources, but if lab test data can be integrated with EMR data, then machine learning and AI can be applied more effectively to guide new personalized medicine tools.

How about hospital outreach labs?
I do not see a bright outlook for hospital outreach growth without hospital leadership recognizing its value and investing in it.

Hospitals have been somewhat successful historically without much investment because they were receiving 3-5 times commercial lab reimbursements. That is changing. Traditionally they had more room to maneuver because they can get lower volume and still be profitable in doing so, especially if they bill effectively. However, price transparency, PAMA and managed care are driving more volume to lower-cost commercial labs (i.e., Quest Diagnostics and Labcorp).

Most hospitals have been unwilling or unable to invest in their outreach businesses, specifically in the systems and resources needed to consistently compete effectively in outreach. Especially today, increasing costs, and labor shortages make it difficult enough to service inpatients, let alone additional volume from outside of the hospital. To compete effectively in outreach requires layering on additional systems and resources such as dedicated leadership, sales, and service teams, as well as improved billing tools. But hospitals are choosing to invest in other areas. Without making these investments in outreach, any higher reimbursement advantages are inconsequential.

Today, hospitals are in survival mode and leadership is, and always will, direct capital resources to areas that move the needle in the moment. The lab has never been a high priority for hospital leadership, and I do not see that changing in the near future. This is apparent given the increasing number of lab outreach transactions [see page 5].

How do you see the lab industry evolving over the next 3-5 years?
The commercial labs are at the forefront in the delivery of the three beacons — cost, quality, and access — that are prerequisites to winning market share. Their role in the transformation of new lab services will expand as advancements are made in using machine learning and AI.

Health systems will continue to outsource to big players to control costs, stay competitive with new technology and advance care with collaboration initiatives. This bodes well for the commercial labs to further their reach into the health system landscape.

In addition, the advancements in point-of-care testing technology could potentially allow for more in-office testing. The determining factors here will be reimbursement and/or the value of cost avoidance that it offers.

Labcorp and Legacy Health Finalize Comprehensive Deal

Labcorp has completed a previously announced transaction (see *LE*, July 2023) with Legacy Health (Portland, OR) to acquire select assets of Legacy's outreach laboratory business. Labcorp also now manages Legacy's inpatient hospital labs through a long-term agreement to provide staffing, leadership, scientific knowledge, analytics and supply chain services. Legacy owns and operates six hospitals in Oregon and southwest Washington as well as 85 physician office clinics and urgent care centers.

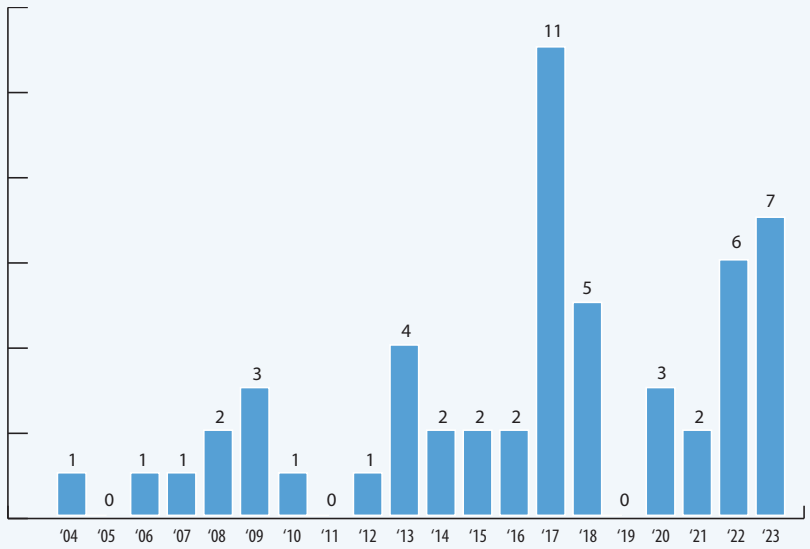
Tufts Deal Expanded

Labcorp finalized its $157 million purchase of the clinical lab outreach business of Tufts Medicine (Boston, MA) in September (see *LE*, August 2023). More recently, Labcorp announced that it will manage Tufts Medicine's three in-patient hospital labs as well.

Hospital Outreach Lab Sales Near Record

Over the past 20 years, there have been a grand total of 54 hospital lab outreach sales transactions. Labcorp has acquired a total of 24 hospital lab outreach businesses, while Quest Diagnostics has acquired a total of 22. Other acquirers have included Solstas Lab Partners (now owned by Quest), Sonic Healthcare USA and LabOne (also now owned by Quest).

Number of Hospital Laboratory Outreach Transactions by Year



Source: *Laboratory Economics*

The greatest number of transactions (11 deals) took place in 2017—just prior to three straight years of 10% rate cuts to the Medicare CLFS due to PAMA. In the past year, a near-record seven hospital lab outreach sales occurred—five deals by Labcorp and two by Quest.

For perspective, it's important to remember that there are more than 3,000 hospitals in the United States that currently provide lab outreach testing services to nonpatients.

Spotlight Interview with Accumen's Jeff Myers

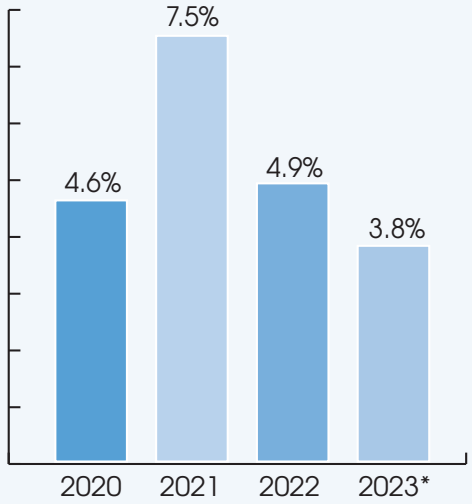
Many health systems are under financial pressure primarily due to rising employee costs and inflation. For example, hospital employees' average hourly earnings grew by 3.8% in the 12 months ended July 2023, according to Fitch Ratings and the U.S. Bureau of Labor Statistics. That's down from the high of 7.5% growth seen in calendar year 2021, but still well above the 2.3% average annual growth for hospital employees from 2010 to 2019. For insight into how this financial pressure is affecting hospital outreach labs, *Laboratory Economics* recently spoke with Jeff Myers, CPA, Vice President, Consulting and Strategic Advisory Services at Accumen Inc. (Scottsdale, AZ).

Jeff Myers, CPA

How is financial pressure at health systems affecting their outreach labs?
More health systems are evaluating the economic and operational value of a potential sale of their outreach labs. At the same time, Quest Diagnostics and Labcorp are aggressively seeking out strategic acquisitions of hospital outreach labs and have been willing to pay higher acquisition prices than in the past. There were a near-record seven outreach lab sales in 2023 (see page 5) and the trend is not slowing down.

How are health systems evaluating the potential sale of their outreach labs?
At the end of the day, it's a basic cash flow analysis assessing the value of cash flows from continuing to operate a service line versus an immediate cash flow. In those cases where hospital outreach businesses have low operating profits (<10%), health system CEOs and CFOs often believe the cash received from a sale can be redirected into a higher-margin business such as an outpatient surgery center.

Annual Growth in Average Hourly Earnings for Hospital Employees



*For 12 months ended July 2023
Source: Fitch Ratings and U.S. Bureau of Labor Statistics

Conversely, there are many hospital outreach labs receiving favorable reimbursement rates (e.g., 3x Medicare CLFS) from private insurers. In these situations, hospital outreach labs can have operating margins in the range of 30% to 35% and are valuable assets to keep.

The key here is developing a credible financial analysis of the hospital lab outreach business. Outreach testing revenue and costs are often intermingled with inpatient/outpatient testing. The sale of an outreach lab is a long-term commitment and should not be undertaken without significant due diligence that supports the decision to sell or hold an outreach lab asset.

What are some other factors that can lead to a successful hospital outreach sale?
Having realistic expectations of the timeline required is crucial, as unattainable timelines can impede a health system's ability to plan and organize a favorable outcome for all stakeholders (patients, providers, employees, etc.). Conversely, too much time can kill a deal, so the right timeline must be addressed from the start of discussions/negotiations.

Why do most hospital outreach labs continue to get paid such high rates?
Most health systems still have leverage with private insurers and have been able to keep their lab

outpatient contracts, including nonpatient outreach testing, tied to their overarching outpatient contract negotiations. This means some health systems continue to be paid for lab testing on a percentage of charges or at fixed contract. Hospital lab outpatient/outreach rates from private payers can average 2x and more above Medicare CLFS rates. In comparison, independent labs at best are getting private-payer rates equal to the Medicare CLFS.

How long will the rate discrepancy between hospitals and independent labs continue? The convergence is happening slowly. Private insurers, including UnitedHealthcare, are slowly pushing hospital outreach labs into separate fee schedule contracts with lower rates.

Chicago Hospitals Getting Paid Up To 23x Medicare CLFS

Federal Regulations put into place in early 2021 require hospitals to provide a consumer-friendly way to examine the prices of 300 "shoppable" services, including at least 14 high-volume clinical lab tests. *Laboratory Economics* examined hospital rates for the Chicago area for CPT 80061 (lipid panel). The information was taken from the price transparency files from each hospital.

The 10 hospitals from Chicago showed high variance in payment rates. Starting with discounted cash price, or the charge that applies to self-paying patients, the lowest rate from the sample was John H. Stronger Hospital (Chicago, IL) at $23.80. The maximum in this category was Thorek Andersonville (Chicago, IL), which charges its cash-paying patients $144.76 for a lipid panel, or more than 10x the current Medicare CLFS rate of $13.39 for CPT 80061

The lowest minimum negotiated charge was only $0.76 paid to Edward Hospital (Naperville, IL) by BCBS of Illinois PPO. The minimum negotiated charge represents the lowest charge a hospital or health system negotiated with all third-party payers for this test.

Similarly, the maximum negotiated charge is the highest charge negotiated with a third-party payer. The highest rate here was $311 paid by BCBS (out of state) to Humboldt Park Health (Chicago, IL). The $311 rate is equivalent to 23x the Medicare CLFS rate for CPT 80061.

Overall, the 10 Chicago hospitals included in our survey had average negotiated third-party rates of between $22.57 (1.7x Medicare CLFS) and $141.36 (10.6x Medicare CLFS).

Hospital Lipid Panel Reimbursement Rates in the Chicago Area

Hospital Name	City	Discounted Cash Price for Self-Paying Patients	Minimum Negotiated Charge	Maximum Negotiated Charge
Advocate Illinois Masonic	Chicago, IL	$67.50	$36.74	$121.50
Advocate Trinity	Chicago, IL	67.50	24.94	121.50
Edward Hospital	Naperville, IL	109.35	0.76	132.65
Humboldt Park Health	Chicago, IL	87.08	13.39	311.00
John H. Stronger Hospital	Chicago, IL	23.80	17.00	$27.20
Loyola University	Maywood, IL	76.57	1.03	232.00
Provident Hospital of Cook County	Chicago, IL	62.30	44.50	71.20
Rush University	Chicago, IL	112.52	16.53	204.79
Silver Cross Hospital	New Lenox, IL	27.00	9.80	54.00
Thorek Andersonville	Chicago, IL	144.76	61.01	137.74
Average Rates		**$77.84**	**$22.57**	**$141.36**

Source: *Laboratory Economics* from Hospitals

MEDICARE CLFS RATES MIGHT BE FROZEN INDEFINITELY (*cont'd from page 1*)
President Biden signed the stopgap funding bill into law on November 16. Without it, Medicare reimbursement for nearly 800 tests on the CLFS was set to be reduced by up to 15% each effective Jan. 1, 2024. In addition, the next PAMA reporting period for applicable labs has been delayed by one year. The next reporting period for private-payer payment data will now be January 1, 2025, through March 31, 2025.

However, based on the way the Congressional Budget Office (CBO) has scored various alternatives, the most likely scenario is continued one-year delays in CLFS rate cuts and PAMA reporting periods.

Scenario 1: The Next PAMA Survey Takes Place as Scheduled
Unlike the first PAMA survey, the second PAMA survey will include private-payer payment data from hospital outpatient labs. Under the new schedule, labs are to report their private-payer payment data (from January 1, 2019-June 30, 2019) to CMS in early 2025. This data will be used to set Medicare CLFS rates for 2026-2028.

Scenario 2: SALSA is Passed into Law
The Saving Access to Laboratory Services Act (SALSA) would require CMS to take a representative sampling of private-payer rates from independent labs, hospital labs and physician office labs (POLs) to determine CLFS rates. SALSA would ensure that the higher rates paid to hospitals are accurately included in CLFS rate calculations.

A preliminary score from the CBO has projected that passing SALSA into law would cost $6 billion over 10 years. A separate analysis by the American Clinical Laboratory Assn. has estimated the cost of SALSA would be less than $3 billion over 10 years.

SALSA (H.R. 2377/S. 1000) currently has the support of 51 House members and four senators.

Scenario 3: CLFS Remains Frozen and PAMA is Delayed
The CBO has scored the one-year delay in payment cuts and reporting as saving $590 million over 10 years. The CBO is convinced that the next private-payer payment survey, which will include hospital outreach rates, will lead to higher CLFS rates. As a result, lawmakers will be prone to freezing the CLFS and postponing the next PAMA survey year after year.

Four years of Medicare CLFS rate freezes may seem like a victory given the 10% per year PAMA rate cuts that took place in 2018-2020. However, lab operating costs have risen substantially over the past few years leading to lower profit margins for most labs.

CMS Approves Medi-Cal Lab Rate Cuts

On November 8, the Centers for Medicare and Medicaid Services (CMS) authorized the California Department of Health Care Services (DHCS) to adjust clinical lab rates resulting from its triennial clinical laboratory private-payer data analysis, retroactively effective July 1, 2023.

The adjustment will lower Medi-Cal fee-for-service rates for 27 high-volume lab and anatomic pathology test codes (see *LE*, May 2023). DHCS says that it is currently updating its Medi-Cal billing and payment system and anticipates the adjusted rates will be implemented in the first quarter of 2024. Once the rates are implemented, DHCS will process an Erroneous Payment Correction to retroactively adjust claims for dates of service on or after July 1, 2023.

The DHCS conducts a lab rate survey every three years. The DHCS rate methodology for lab and pathology services is the lesser of the weighted survey rates or 80% of current Medicare rates. The next survey period will rely on private-payer rates paid to California labs in calendar year 2024.

Spotlight Interview with GYN PATH's Anita Miles

GYN PATH Services (El Paso, TX) is an independent lab focused on women's health testing, including Pap and HPV screening, PCR-based testing for STIs and bacterial vaginosis, and anatomic pathology. GYN PATH has 26 employees, including its Medical Director, Octavio Trejo, MD, FCAP, and serves approximately 200 physicians in southwest Texas. *Laboratory Economics* recently spoke with Anita Miles, Executive Director at GYN PATH.

Anita Miles

Who founded GYN PATH Services?
My father Philip A. Miles, MD, FACOG, FCAP, age 85, founded GYN PATH back in 1982 after serving in the army. He was initially board certified in Ob/Gyn but developed multiple sclerosis as a young adult, which hindered his ability to practice as an Ob/Gyn. So, he got a second board certification in pathology and opened the laboratory. He is retired now, but still occasionally fills in for Dr. Trejo.

I was 15 years old when I started working at GYN PATH. In the early days, I was the company's sole courier, specimen processor and biller. I became Executive Director in 1998.

Can you describe your experience during the pandemic?
GYN PATH was fortunate to have three Hologic Panther PCR analyzers in operation prior to the pandemic. At various pandemic peaks, we were performing up to 2,000 Covid tests per day with turnaround times of less than 24 hours. In total, we have performed 300,000 Covid tests. Currently, we're performing an average of about 50-75 Covid/flu/RSV test panels per day primarily for symptomatic patients.

Any plans for test menu expansion?
Yes. Earlier this year we moved into a newly renovated 12,000-square-foot lab and office building. We designated space for a fine needle aspiration (FNA) room where Dr. Trejo will see patients and collect breast and thyroid needle biopsy specimens. We've also invested in a Roche CINtec Plus cytology system and will be hiring another pathologist and cytotechnologist soon.

What prompted your decision to expand into FNAs?
Dr. Trejo is trained in fine needle aspirates and has a special interest in this field. We felt there was a need to offer referring physicians and patients the ability to have the FNA obtained the same day the lump was found. Referring physicians can notify Dr. Trejo and immediately send their patients to our laboratory.

Is GYN PATH back to its pre-pandemic test volumes?
We're currently performing 100,000 billable tests per year, including approximately 30,000 Pap tests, which is basically back to our pre-pandemic levels.

How do you compete against the national labs (Quest, Labcorp and Sonic)?
Faster turnaround time (<24 hours) and better customer service. For example, our physician clients can call Dr. Trejo's cell phone directly with questions.

Have you seen any price inflation for lab supplies and/or equipment?
Vendors have raised shipping prices and tacked on fuel surcharges. These charges often exceed the price of the products we order.

What's your biggest challenge?
The increase in managed care Medicare and Medicaid plans that favor the national labs. It seems like new managed care plans are being launched every month and gaining in-network access is a challenge.

Quest Diagnostics Invests in Blood-Based Colorectal Cancer Test Maker

Universal Diagnostics (Madrid, Spain and Cambridge, MA) has raised $70 million from a Series B financing round that included Quest Diagnostics. In addition, Quest has obtained exclusive rights to market Universal Dx's "Signal-C" colorectal cancer screening blood test in the United States after the test gets FDA clearance.

The Signal-C test detects methylated DNA patterns and fragments released by colorectal cancer tumors that circulate in the bloodstream.

Universal Dx will soon begin a pivotal 15,000-patient study of its Signal-C test at 100 investigator sites. Quest's oncology reference lab in Lewisville, Texas will perform the testing to support this study. Study results will be used to support a premarket FDA application. The target market for Signal-C is average-risk patients visiting their primary care physician.

Earlier this year, Universal Dx reported that a prospective study of 997 patients showed that the Signal-C test can detect early-stage colorectal cancer with 93% sensitivity and precancerous lesions (advanced adenomas) at 54% sensitivity with overall specificity of 92%. These results are better than Exact's Cologuard stool test which has 42% sensitivity for detecting advanced precancerous lesions and 24% sensitivity for the fecal immunochemical test (FIT).

Univeral Dx has now raised a total of more than $100 million since being founded in 2012. The company's founder is entrepreneur Juan Martínez-Barea, Executive Vice President.

CRI Genetics Testing to Pay $700K for Deceptive Marketing

The Federal Trade Commission (FTC) says that CRI Genetics (Santa Monica, CA) will pay $700,000 to resolve allegations of deceptive marketing tactics, including misleading customers about the accuracy of its DNA testing and ancestry services to consumers.

CRI Genetics, which also does business as OmniPGx, operates websites that sell DNA testing services directly to consumers at prices that range from $99 to $199. CRI contracts with an unnamed third-party laboratory for actual testing. CRI's revenue from 2017 to 2021 was as much as $42.8 million, according to the FTC. CRI's founder and owner is Oleh Mulyar (aka Alex Mulyar).

The FTC alleged that CRI falsely advertised that its tests were more accurate than competitors. CRI also hosted websites posing as independent reviewers of DNA ancestry tests that rated CRI as the best option. The company also posted fake reviews on its own website and social media platforms like Facebook that were passed off as independent testimonials, according to the FTC.

The FTC alleged that CRI also used pop-up screens to add expensive add-on services to consumer purchases, including a celebrity report that CRI claimed would match consumers' DNA with those of famous people.

CRI must pay the $700,000 in civil penalties, secured by commercial property, over four years. CRI has also agreed to reform its advertising practices.

XiFin Payor Rate Transparency Monitor Sheds Light on Lab Rates

As required by federal price transparency rules, health insurance companies have begun making public huge data files with detailed information on their contracted rates for lab tests and other services. However, these data files are often so large and unwieldy that they are almost unusable.

But XiFin Inc. (San Diego, CA) has condensed this data into a free user-friendly online tool that can be viewed by anyone. The Payor Rate Transparency Monitor compares contracted rates (highs, lows and weighted averages) for 23 high-volume lab tests by UnitedHealthcare, Aetna and Cigna.

Labs can use this data to inform rate negotiations with their lower-paying health plan contracts, or for decisions to go out of network, notes Jeff Carmichael, Senior Vice President of Engineering and Analytics at XiFin.

Among other things, the XiFin Monitor highlights the absurdity that can be found in lab test reimbursement rates. For example, Cigna's lowest contracted rate for a basic metabolic panel is $0.10, while its most-frequent rate is $4.22, and its highest rate is $999.99—all for the same test.

The data analyzed by the XiFin Monitor is a result of the Health Plan Transparency in Coverage Rule. This rule requires payors to provide data files of billing codes for all agreed-upon in-network and out-of-network reimbursement rates on a public website. The purpose is to help consumers shop for healthcare services.

Cigna Negotiated Contract Rates for 12 High-Volume Lab Test (November 2023)

CPT Code	Description	Lowest Negotiated Rate	Most Frequent Negotiated Rate	Weighted Average	Highest Negotiated Rate
80048	Basic metabolic panel	$0.10	$4.22	$28.98	$999.99
80050	General health panel	$0.26	$60.78	$60.49	$468.22
80053	Comp metabolic panel	$0.14	$5.36	$32.20	$247.82
80061	Lipid panel	$0.19	$31.00	$38.73	$326.60
80307	Drug test(s), presumptive	$0.83	$50.00	$79.79	$594.10
81001	Urinalysis	$0.05	$3.84	$13.02	$159.00
82306	Vitamin D	$0.36	$14.77	$54.78	$436.79
82570	Creatinine	$0.08	$2.60	$18.08	$159.00
82607	Vitamin B-12	$0.19	$7.47	$30.86	$220.32
82728	Ferritin	$0.18	$16.36	$34.36	$200.68
82746	Folic acid	$0.20	$7.31	$33.00	$216.36
84443	Thyroid stim hormone (TSH)	$0.20	$16.02	$34.82	$247.90

Source: XiFin Inc. (https://www.xifin.com/resources/payor-rate-transparency-monitor/)

Principle Health Systems Acquires BioStat Laboratory

Principle Health Systems (Houston, TX) has acquired BioStat Laboratory (Addison, TX) for an undisclosed sum. Founded in 2017, BioStat Laboratory operates a CLIA-certified lab in the Dallas area that provides lab testing and phlebotomy services to nursing home, assisted living and home health patients. Principle Health Systems (LBN Concord Life Sciences) operates a CLIA-certified lab in Houston that is also focused on long-term care and home health patients.

Lab Stocks Off 9% Year to Date in 2023

Twenty-four lab stocks have fallen by an unweighted average of 9% year to date. In comparison, the S&P 500 Index is up 23% year to date. The top performing lab stocks have been NeoGenomics, up 113%; Natera, up 47%; and Myriad Genetics, up 43%. Labcorp is up 9% to date and Quest is down -14%.

Company (ticker)	Stock Price 12/15/23	Stock Price 12/30/22	2023 Price Change	Enterprise Value ($ millions)	Revenue for Trailing 12 mos. ($ millions)	Enterprise Value/ Revenue
NeoGenomics (NEO)	$19.66	$9.24	113%	$2,750	$575	4.8
Natera (NTRA)	59.01	40.17	47%	6,750	989	6.8
Myriad Genetics (MYGN)	20.74	14.51	43%	2,000	734	2.7
Exact Sciences (EXAS)	65.90	49.51	33%	14,100	2,406	5.6
Opko Health (OPK)	1.55	1.25	24%	1,420	867	1.6
Veracyte (VCYT)	28.17	23.73	19%	1,890	343	5.5
Labcorp (LH)	219.50	202.30	9%	24,650	15,071	1.6
Sonic Healthcare (SHL.AX)*	31.63	29.97	6%	17,350	8,146	2.1
Guardant Health (GH)	28.19	27.20	4%	3,680	536	6.9
Interpace Biosciences (IDXG)	1.06	1.04	2%	60	38	1.6
Fulgent Genetics (FLGT)	28.18	29.78	-5%	7	286	0.02
Enzo Biochem (ENZ)	1.33	1.43	-7%	-8	32	NA
DermTech Inc. (DMTK)	1.55	1.77	-12%	40	14	2.8
CareDx (CDNA)	9.97	11.41	-13%	354	297	1.2
Quest Diagnostics (DGX)	135.03	156.44	-14%	20,320	9,297	2.2
Castle Biosciences (CSTL)	20.07	23.54	-15%	339	192	1.8
Biodesix (BDSX)	1.57	2.30	-32%	176	44	4.0
Exagen (XGN)	1.55	2.40	-35%	24	52	0.5
Psychemedics (PMD)	3.02	4.90	-38%	18	23	0.8
Aspira Women's Hlth (AWH)[1]	2.79	4.95	-44%	26	9	2.8
ProPhase Labs (PRPH)	4.50	9.63	-53%	96	63	1.5
Invitae (NVTA)	0.62	1.86	-67%	1,440	482	3.0
GeneDx (WGS)[2]	2.43	8.71	-72%	22	207	0.1
Biocept (BIOCQ)[3]	0.06	15.90	-100%	5.2	1.4	3.7
Totals & Averages			**-9%**	**$97,508**	**$40,702**	**2.4**

1) Aspira had a 1-for-15 reverse stock split on May 11. 2) GeneDx had a 1-for-33 reverse stock split on May 4.
3) Biocept had a 1-for-30 reverse stock split on May 16.
*Sonic Healthcare's figures are in Australian dollars

Source: *Laboratory Economics* from SeekingAlpha.com

Jondavid Klipp, Editor and Publisher Jennifer Kaufman, Associate Editor Harrison Klipp, Data Analyst

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About the Author

Jondavid Klipp is president and publisher of ***Laboratory Economics LLC***, an independent market research firm focused on the business of laboratory medicine. Prior to founding ***Laboratory Economics*** in April 2006, Mr. Klipp was managing editor at Washington G-2 Reports. During his seven-year employment with G-2, he was editor of Laboratory Industry Report and Diagnostic Testing & Technology Report. Mr. Klipp also authored several landmark research reports, including ***G-2's Lab Industry Strategic Outlook 2005, U.S. Laboratory Reference Testing: Profile and Pricing Trends*** and ***The Laboratory Market Leaders Report***. Prior to joining G-2, Mr. Klipp was an HMO analyst at Corporate Research Group in New Rochelle, New York, and a senior writer in the equity research department at Dean Witter in New York City.

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