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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

Special New Year's Report:
Lab Execs Share Outlook for 2024

For an inside look at what may be in store for the clinical lab industry this year, *Laboratory Economics* interviewed the top executives at a diverse group of 11 lab companies. Consensus trends identified include 1) there is a critical shortage of pathologists and lab employees (phlebotomists, couriers, front-end processors, MLT/MTs, etc.); 2) vendors are pushing through price increases for reagents and other lab consumables; 3) gaining in-network access is the biggest challenge for smaller labs; and 4) the transition to digital pathology combined with AI is undeniably in progress. *Continued on pages 3-8.*

UnitedHealthcare Z-Code Start Date: April 1

UnitedHealthcare (UHC) has announced that its "Z-code" requirement for certain genetic test claims submitted to its commercial health plans will become effective on April 1, 2024. UHC's new Z-code requirement will initially cover 133 CPT codes as well as 104 proprietary lab analysis (PLA) codes.

Commercial claims for these test codes will be denied if the Z-code information is missing, invalid or does not match the service represented by the CPT code reported on the claim, according to a UnitedHealth policy bulletin issued in early January.

But this is only "Wave I." UHC is likely to add the Z-code requirement to certain PCR-based microbiology test claims for commercial plans within the next ~12 months as well, notes Ann Lambrix, Vice President, RCM Solutions at Lighthouse Lab Services (Charlotte, NC).
Full details on pages 9-10.

Quest Buys Steward Outreach Lab Business in PA & OH

Quest Diagnostics has acquired select assets of Steward Health Care System's outreach lab business in Pennsylvania and Ohio. Acquired clinical lab test volumes will be shifted to Quest's regional lab in Pittsburgh. In addition, Quest will acquire assets from Steward's lab business that serves Hawthorn Medical Associates (Dartmouth, MA), pending the transfer of the laboratory license. *Cont'd on page 2.*

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QUEST BUYS STEWARD OUTREACH LAB BUSINESS IN PA & OH (*cont'd from page 1*)
The outreach lab asset sales are related to two Steward hospitals: Trumball Regional Medical Center (Warren, OH—214 beds) and Sharon Regional (Sharon, PA—213 beds).

Quest already has a long-standing relationship with Dallas-based Steward that includes providing lab management services and previous outreach lab purchases. In 2009, Quest acquired Caritas Medical Laboratories (Boston, MA), an affiliate of Caritas Christi Health System (Steward acquired Caritas in 2010). And in 2014, Quest paid $34 million to acquire the remainder of Steward's outreach lab service operations in New England.

The most recent sale follows reports that Steward, which operates 33 hospitals in eight states, owes more than $50 million in unpaid rent to Medical Properties Trust (MPT), which owns 437 hospitals with 43,000 beds in nine countries.

Steward, which leases more than 30 facilities across six different markets from MPT, is MPT's largest tenant. Steward accounts for more than 20% of MPT's annual revenue of $1.4 billion. MPT also has a 10% equity stake in Steward.

MPT has stated that its management and advisers have worked closely with Steward to develop an action plan that includes the "potential sale or re-tenanting of certain hospital operations" and "divestiture of non-core operations."

Providence Closing Outreach Lab Service in California

Providence St. Joseph Health (Renton, WA) has announced that it is closing its hospital outreach lab service line in California effective March 15, 2024. In a January 11 press release, Providence said:

> Following a thorough assessment, Providence has announced that it will close the outpatient lab service line, which supports community outreach at several hospitals throughout California. This change will help us focus on our strengths of delivering care and partnering with other organizations whose primary business is lab services…. We did not enter this decision lightly and are confident that other providers of these services will be able to support our community's future needs.

Providence owns 11 hospitals in southern California and six hospitals in northern California.

Providence has not yet announced which organization will be taking over its outreach business in California. However, Labcorp seems like the obvious candidate.

In August 2023, Providence Oregon closed a deal for Labcorp to acquire Providence Oregon's outreach lab services and select assets for $110 million. Providence Oregon has maintained operation and ownership of certain anatomic pathology and genomics outreach testing and its hospital labs in the region (see *LE*, June 2023).

In the nine months ended Sept. 30, 2023, Providence reported a net loss of $613 million versus a net loss of $5.9 billion in the same period a year earlier; revenue was up 8.3% to $21.2 billion. Its biggest expense—salaries and benefits—increased by 5.8% to $11.3 billion; supply costs were up 9.6% to $3.3 billion.

Providence owns a total of 51 hospitals and more than 1,000 clinics serving patients in seven Western states – Alaska, California, Montana, New Mexico, Oregon, Texas, and Washington.

2024 OUTLOOK FOR LABS: 11 EXECUTIVE PERSPECTIVES (*cont'd from page 1*)

The merger of Advocate Aurora Health and Atrium Health in late 2022 doubled the size of **ACL Laboratories** (West Allis, WI), notes ACL President **Dan Mumm**. The combined lab enterprise now includes 5,100 employees working at three core labs (Charlotte, Chicago and Milwaukee) and 70 rapid response labs. ACL Labs performed a total of 60 million tests last year. Growth in the southeast market (NC, SC, GA & AL) was fastest at 15-25% in 2023, while test volume growth in the Midwest (Il & WI) was approximately 1-4%, according to Mumm.

Dan Mumm

Mumm recognizes that some health systems are selling their outreach labs to shore up their financials. However, he notes that the merged health system (Advocate Health) is doing fairly well financially, and management recognizes the strategic long-term importance of ACL Labs.

Priorities for 2024 include cost savings and growth synergies such as consolidating ACL Labs vendor contracts for better pricing. This includes consolidating reference lab services currently provided by two vendors: ARUP Labs and Labcorp.

ACL Labs is also in the process of developing a genetic testing center of excellence that will focus on next-gen sequencing for oncology and pharmacogenomic testing. In addition, this center of excellence will help bring research developed at its affiliated academic medical center Wake Forest Baptist to the clinical market. The location of this lab hasn't been finalized yet.

Mumm believes that the FDA's plans to regulate laboratory-developed tests, assuming a final rule, will be challenged by industry lawsuits. While there may be some existing loopholes that should be closed, any new LDT regulation should come from CLIA, according to Mumm.

Another major new initiative underway at ACL Labs is the transition to digital pathology. Slide scanners will be installed at locations to be determined in the Midwest and Southeast. ACL labs contracts with six different pathology groups and has one employed group based at Wake Forest Baptist. The plan is to add AI tools, which will provide the ROI, over the course of the next 2-3 years, notes Mumm.

ARUP Laboratories (Salt Lake City, UT), which has nearly 5,000 employees, is having a tough time finding medical technologists, notes Chief Executive **Andy Theurer**. He cites Utah's low unemployment rate (<3%).

Andy Theurer

Last year, ARUP and the University of Utah's Division of Medical Laboratory Sciences secured $3 million in federal funding to build a new Advanced Practice Clinical Laboratory Training Center. The center should open later this year and will help train 80 new MTs per year. "We could hire all 80 grads every year and we'd still need more," says Theurer.

The shortage is also spurring ARUP to accelerate its investments in digital pathology and AI—both for anatomic pathology and slide-based clinical lab testing (e.g., ARUP developed the first-ever AI-powered ova and parasite test.). Theurer says that AI programs that highlight areas of interest have the potential to double the efficiency of pathologists and microbiology technologists.

Other challenges include inflation. Theurer, who was named CEO in June 2021 after more than 30 years in various executive leadership roles at ARUP, says vendors have

sought price increases of anywhere between 5% and 30% for reagents and supplies over the past two years.

Test menu expansion at ARUP is focused on mass spectrometry, toxicology, anti-neuronal antibody testing, cytogenetics and next-gen sequencing.

Late last year, ARUP created the new ARUP Institute for Research and Innovation in Diagnostic and Precision Medicine. The institute is being headed by Tracy George, MD, ARUP Chief Scientific Officer, and focuses on vendor collaborations to help develop and bring new tests to the clinical market.

Theurer says that FDA regulation of LDTs will lead to a small number of high-volume LDTs getting FDA clearance followed by higher test prices. Clinical laboratories will have to drop thousands, if not tens of thousands, of small-volume LDTs from test menus. The net result will be higher costs and worse patient care. "For the life of me, I can't figure out who is behind this."

Separately, Theurer believes that health systems are selling their labs solely for short-term financial gains. "Many health system CEOs and CFOs don't fully understand the importance of retaining control of their lab because of the critical information it contributes to care. They also don't understand how profitable their labs are, or how much they enhance their brand…. Five years from now these decision makers will have regrets, but building back a lab from scratch is not easy."

Mayo Clinic Laboratories (Rochester, MN) is making steady progress in its transition to digital pathology, according to Chief Executive **William Morice, MD, PhD**. Approximately 50% of its surgical pathology cases on the Mayo Clinic Rochester campus are being digitized, these cases are interpreted by pathologists via computer monitor.

Mayo Clinic Rochester employs 180 staff pathologists and PhD scientists. It's using Leica/Aperio GT450 scanners with the Sectra digital pathology system.

William Morice, MD, PhD

Morice notes that the transition to digital is nearly 100% at Mayo's hospital-based labs in Wisconsin, Arizona and Florida. In addition, Mayo is in the process of digitizing its archive of several million glass slides using Pramana scanners with robotic slide loading and automated quality control to allow for high throughput scanning.

Morice says that digital pathology will improve quality and increase pathologists' productivity through workflow efficiencies and the ability to apply AI algorithms. Mayo is working with Techcyte (Orem, UT) to develop AI algorithms for both anatomic pathology and clinical lab applications. Mayo and Techcyte are also developing a digital pathology software platform that integrates digitized image management and AI applications.

Mayo Clinic Laboratories, which performed approximately 27 million tests in 2023, typically adds 100 new tests to its menu every year. Morice says that test menu expansion is focused on serious and complex diseases such as genetic markers for inheritable cardiovascular disease, autoimmune neurology, and next-generation genetic sequencing for difficult-to-characterize infectious diseases of the central nervous system.

PathGroup (Brentwood, TN) plans to shift to digital pathology interpretations on an enterprise-wide scale over the next few years, according to Chief Executive **Ben Davis, MD**. Over the past three years, approximately 30% of PathGroup's 250 pathologists have

switched to full digital reads. PathGroup currently has a total of 28 scanners at six locations. Davis says that the transition would be faster, but scanners have been in short supply over the past two years.

"We expect to be a front runner in the implementation of AI tools that demonstrate improved professional quality as well as productivity gains and cost efficiency," says Davis. He expects AI tools to be implemented initially for quality control (double checking pathologist interpretations) and later for assistance with primary diagnosis. He expects the adoption of digital pathology and AI to help with the long-term shortage of expert pathologists. A key question is whether the FDA will require premarket clearance of AI support tools.


Ben Davis, MD

Davis believes that the FDA's desire to regulate all laboratory-developed tests is not practical. The FDA does not have the capacity to regulate all ~100,000 LDTs and may need to narrow its scope to molecular oncology and companion diagnostics, according to Davis.

After the pandemic subsided, Davis says that PathGroup redirected its PCR testing capacity back into women's health and infectious disease testing, including HPV and gonorrhea/chlamydia. "We stuck with tests with established clinical utility and known payer reimbursement."

Regarding inflation, Davis notes that "Every supplier came to us with price increases in 2023....In most cases we have been able to moderate these price hikes."

Growth, both organically and by acquisitions, remains a strategic goal for PathGroup in 2024, according to Davis.

Originally founded by pathologists in 1965, PathGroup has grown to become the nation's largest privately-held lab company. PathGroup, which currently has 2,000 employees and annual revenue of $575 million, is owned by GTCR, company management and pathologists.

Aculabs Inc. (East Brunswick, NJ) has most recently been expanding into southern New York, according to President **Peter Gudaitis**. Aculabs, which has 300 employees and test volume of ~19 million per year, serves more than 500 long-term care facilities in the northeast.

Gudaitis says that commercial lab acquisitions of hospital outreach labs often result in the shedding of their nursing home clients. In addition, some health systems are choosing to exit the nursing home outreach testing business because of its low margins.


Peter Gudaitis

Gudaitis says that Aculabs is adding as many as 10-20 new clients per month. The biggest challenge is finding and hiring mobile phlebotomists to keep up with growth. Aculabs, which employs approximately 200 phlebotomists, recently developed its own scheduling software app to maximize phlebotomist efficiency. Wage rates for phlebotomists average between $18 and $24 per hour in the New Jersey/New York area, according to Gudaitis.

Gudaitis says he's seen across-the-board inflation for delivery services, supplies and employee health insurance. He notes that New Jersey raised its minimum wage by $1 to $15.13 effective January 1, 2024.

Gudaitis' goals for 2024 include potential expansion into Boston, Buffalo/Rochester and Pittsburgh. Aculabs is also hoping that it can help more nursing home clients introduce bedside point-of-care analyzers (e.g., Abbott's i-STAT) for stat testing requests.

The biggest challenge at **Southeast Clinical Labs** (Birmingham, AL), which has 90 employees and performs 1.4 million billable tests per year, is gaining in-network status with all payers in its region (Alabama, Mississippi and Georgia), according to Chief Executive **Steve Boyd**.


Steve Boyd

About 20% of SCL's test volume is currently billed as out-of-network. Nearly all payers are now routinely requiring medical records to support out-of-network lab test claims. And the extra work to meet these demands does not guarantee payment, notes Boyd.

Other challenges include finding employees, especially phlebotomists and couriers.

Boyd also notes that nearly all of SCL's suppliers are instituting annual price increases, with some reagents and supplies going up as much as 20%. Vendors have also introduced new shipping charges. That's something I've never seen before," says Boyd.

Goals for the new year include bringing 50 tests in-house, including electrophoresis-based immunoassays. Other goals include gaining more in-network insurance contracts and renegotiating vendor contracts (especially shipping charges).

Despite challenges, Boyd says SCL is able to remain competitive by offering high service levels to physician clients including 1) custom test groupings and service especially for pediatricians and oncologists; and 2) answering all phone calls with a live person who answers 90% of questions without transferring the call.

SCL was founded in 2014. It's the third independent lab that Boyd has helped found. Previously, he started LabSouth (sold to Dynacare in 2000) and Southern Diagnostics (sold to Solstas Lab Partners in 2011).

Quantum Pathology (Waltham, MA) plans to install a whole slide imaging scanner within the next few months, according to President and CEO **Erik DiGuilio**. The move into digital pathology will allow Quantum to start marketing technical services (slide-prep and digitized slide images) on a national basis.

The majority of Quantum's clients are currently urology, gastroenterology, dermatology and podiatry practices in the New England region (CT, MA, ME, NH, VT and RI).

Quantum was co-founded by DiGuilio and Chief Medical Officer May Azar, MD, in 2014. Quantum currently has 50 employees, including 10 pathologists, and processes roughly 80,000 patient cases per year which translates to approximately 110,000 specimens per year. Volume is up roughly 25% from pre-pandemic levels, according to DiGuilio.


Erik DiGuilio

DiGuilio says the biggest challenge to expanding geographically is gaining access to in-network insurance contracts. Quantum has been using Credentials Administrative Services (Bristol, NH) to help with applying for new managed care contracts. Applications include advocacy letters from Quantum clients. CAS is paid a bonus for each contract it helps win. Persistence is also needed. Quantum has applied as many as 10-12 times before gaining in-network status with some payers, according to DiGuilio.

In addition to being CEO, DiGuilio acts as the primary sales rep for Quantum. Referrals from existing physician clients are the primary source of new clients. A top selling point is open communication—clients have direct cell phone and text access to both DiGuilio and Quantum's pathologists.

TriCore Reference Labs (Albuquerque, NM) is holding back on test menu expansion as it awaits the FDA's next move on LDT regulation, according to President & CEO **Robin Divine**. TriCore, which performs approximately 12 million tests per year, has a test menu with more than 2,900 tests.

LDTs are a crucial part of TriCore's test menu, especially in areas of precision medicine such as infectious disease, cancer care, and transplant testing and are already highly regulated under CLIA, notes Divine. She says that TriCore's ability to respond to future health threats (such as pandemics, drug testing, etc.) will be hobbled due to regulatory morass and application fees. If the FDA's proposed rule holds, many TriCore LDTs will have to be sent out to national labs, resulting in decreased and delayed access to timely results and treatments,


Robin Divine

TriCore is an independent regional laboratory, serving New Mexico's three largest health systems — Presbyterian Healthcare, UNM Health and Lovelace Health System — for a combined total of 16 hospitals. In addition, TriCore serves over 5,000 clinics and independent physician offices throughout New Mexico. Its main laboratory is in Albuquerque, and it operates a satellite lab in Las Cruces. TriCore also has 40 patient service centers across the state.

TriCore is currently using digital pathology mostly for IHC testing and expanding into quantification image analysis. Pathology interpretations are performed by two groups, Pathology Associates of Albuquerque and University of New Mexico Pathology. Primary digital pathology interpretations can be done. However, Divine says that TriCore is limited by the cost of scanners, which remain a barrier to full transition.

At the end of 2023, TriCore joined the Atalan network. Atalan operates a tech-enabled platform that gives doctors and medical centers access to a national network of labs. Divine is hoping that Atalan will enable TriCore to expand its reference testing services more readily outside New Mexico.

Finally, Divine says that TriCore is planning to launch a direct-to-consumer lab testing product line in 2024.

ACM Global Laboratories (Rochester, NY), which has 675 employees, operates two business segments: toxicology testing and central lab testing services to support clinical trials for pharmaceutical and biotech companies, according to President **Ken Babineau**. Overall volume is approximately 14 million tests per year.


Ken Babineau

ACM's toxicology testing lab (dba DrugScan) is based in Horsham, Pennsylvania. Babineau notes that FDA regulation of LDTs has the potential to significantly impact smaller toxicology labs. In particular, premarket review will raise costs and lengthen the time it takes toxicology labs to add novel psychoactive drugs (e.g., deadly Fentanyl analogs and Xylazine tranquilizers) to test panels. ACM's goals for 2024 include launching a new software tool to help health systems manage and track patients in opioid treatment programs, notes Babineau.

ACM's central lab services business owns labs in Rochester, NY, United Kingdom and Singapore. Babineau says that ACM was able to grow despite a slowdown in R&D spending by biotech that occurred in 2022-2023. And there are signs that R&D spending is beginning to pick up. Goals for 2024 include expanded bioanalytical testing and enhanced global market coverage.

Baylor Genetics (Houston, TX) saw double-digit growth and performed several hundred thousand genetic tests in 2023, according to Chief Executive **Kengo Takishima**. Baylor Genetics operates a 73,000-square-foot laboratory with 300 employees based at Texas Medical Center. The lab specializes in rapid whole genome sequencing (WGS), chromosomal microarray testing (CMA), carrier screening, non-invasive prenatal testing, hereditary cancer and disease-specific panels.

Kengo Takishima

In 2023, Baylor Genetics launched four new panels, including a neuromuscular disorders panel, two epilepsy panels, and a neurodevelopmental disorders panel, as well as enhancements to its WGS, GeneAware carrier screening, CMA, FISH analysis and hereditary cancer panels.

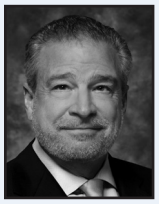
This year Baylor Genetics plans to add new tests in areas such as RNA sequencing. Takishima says that the company is also working to streamline its online ordering, sample collection, tracking and customer support.

Baylor Genetics is a joint venture between H.U. Group Holdings (formerly Miraca Holdings) and the Baylor College of Medicine.

Caris Life Sciences (Irving, TX) is actively working to expand the application of its liquid-biopsy platform ("Caris Assure") for multi-cancer early detection, minimum residual disease and therapeutic monitoring, according to Chairman and CEO **David Halbert**, DSc (h.c.). He expects a peer-reviewed manuscript that addresses the broader applications of Caris Assure to be published later this year.

Caris Assure was launched as an LDT in 2022. The test uses whole exome and whole transcriptome sequencing to analyze 23,000 genes from whole blood. Caris Assure, which has a Z-code (Z00M0), is currently being used to guide treatment selection for cancer patients. Caris opened a new 35,000-square-foot lab dedicated to liquid-biopsy testing in Phoenix in April 2022.

To date, the biggest challenges with liquid biopsies have been 1) poor sensitivity; 2) false positives; and 3) limited gene coverage, notes Halbert. He believes that Caris Assure has addressed each of these problems, resulting in (compared to tissue profiling) 94% sensitivity and 99.9% specificity, with 96.8% positive predictive value (PPV).



David Halbert

Caris's other flagship product is MI Tumor Seek Hybrid (Z01V0; $3,500), a tissue-based genomic profiling test that uses sequencing to guide clinical decision-making for oncology patients with advanced solid tumors.

Caris, which has 1,800 employees, has raised approximately $1.7 billion from outside investors since 2018. Its backers include Highland Capital Management, Sixth Street Partners, OrbiMed and Braidwell.

UNITEDHEALTHCARE Z-CODE START DATE: APRIL 1 (*cont'd from page 1*)

Z-codes are five-character alpha-numeric codes assigned to molecular diagnostics tests by Palmetto GBA's MolDX program. Z-codes are used in conjunction with CPT codes on lab test claims. Z-codes are housed in a test registry catalog called the DEX Diagnostics Exchange that is managed by the MolDX program.

UHC first announced its Z-code requirement for commercial test claims back in spring 2023 with an initial effective date of August 1, 2023. This was then delayed until October 1, 2023, and then delayed again. The new effective date of April 1 is likely to stick. UHC currently covers a total of 27.3 million commercial health plan members in the United States.

"Since we delayed the initial effective date, we've worked with providers offering assistance as they register for Z-codes and are continuing to do so. We will continue to reach out to providers with reminders and status updates," according to UHC spokesperson Tracey Lempner. She says that the Z-code requirement will result in UHC paying claims more accurately with fewer requests for medical records.

Ann Lambrix

"It's going to happen," says Lighthouse's Lambrix. "Labs that have buried their heads in the sand and not made preparations are going to regret it." She says that obtaining a Z-code and passing technical and clinical utility assessments can take anywhere from a few months to a year to complete. The biggest roadblock to completing the Z-code process has been providing documentation and/or published peer-reviewed studies that demonstrate a test's clinical utility and positive effect on patient treatment.

In addition, Lambrix says that genetic tests billed using CPT 81479 (Unlisted molecular pathology procedure) without an established Medicare rate are having difficulty.

UHC's Z-code requirement is initially focused on pharmacogenomic and cancer genetic testing, according to William Baus, President of the billing management firm Lab Revenue Navigator (Carrollton, TX). But he expects the list of codes to be expanded to include PCR-based testing for respiratory infections (e.g., CPT 87631-87633, 87636, 87637, etc.) and gastroenterology diseases (e.g., CPT 87154, 87483, 87505-87507) in the near future. He also expects PCR-based tests for urinary tract infections (UTIs), wound care, nail fungus and skin infections to be added over time as well.

William Baus

Baus says that labs are charging between $500 to $900 for PCR test panels versus $15 to $30 for traditional culture-based microbiology tests. UHC and other payers are concerned that PCR testing is so sensitive that it's picking up dead pathogen fragments that are unrelated to active infections. Payers believe this can lead to treatment of an infection that doesn't exist, notes Baus.

Which labs will be affected by UnitedHealthcare's Z-code requirement?

In addition to Palmetto GBA, there are three other Medicare Administrative Contractors (MACs)—Noridian, WPS and CGS—that already use MolDX and Z-codes for their Medicare Part B test claims. In addition, UHC has already been requiring Z-codes for its Medicare Advantage claims for nearly two years. UHC currently covers 7.6 million Medicare Advantage members nationwide. Labs serving these MAC jurisdictions and UHC Medicare Advantage members should be well-prepared for UHC's new Z-code requirement for commercial members.

However, labs located in the three MAC regions not participating in MolDX will need to get Z-codes in order to get paid for genetic tests they perform on UHC commercial members.

The three non-participating MACs are National Government Services (IL, MA, NY, etc.), Novitas (MD, NJ, PA, TX, etc.) and First Coast (Florida and Puerto Rico).

Which test codes will be affected by UnitedHealthcare's Z-code requirement?
As previously mentioned, UHC's new Z-code requirement for commercial claims will initially cover 133 CPT codes as well as 104 proprietary lab analysis (PLA) codes. Many of these codes are rarely used and have minimal volume.

To get a handle on the most frequently ordered tests on UHC's Z-code requirement list, *Laboratory Economics* analyzed each test codes' Medicare Part B allowed volume for 2022. At the top of the list is CPT 81479 (Unlisted molecular pathology procedure) with Part B volume of 201,721 tests and payment of $477 million.

Other high-volume tests on the list include CPT 81279 (JAK2 gene targeted sequence analysis) with part B volume of 29,213 tests and payment of $5.4 million. And CPT 81455 (targeted genomic sequence analysis panel) with Part B volume of 25,685 tests and payment of $75 million.

Top 25 Tests Targeted by UHC by Medicare Part B Allowed Volume for 2022

Code	Description	Part B Allowed Volume 2022	Part B Allowed Payment 2022
81479	Unlisted molecular pathology procedure	201,721	$476,723,962
81279	JAK2 gene targeted sequence analysis	29,213	$5,373,201
81455	Tgsap so/hl 51/> DNA/DNA&RNA	25,685	$74,737,604
81206	BCR/ABL1 gene major bp	25,245	$4,127,820
81519	Oncology breast mRNA	24,508	$94,911,784
81209	BLM gene	22,646	$890,072
81238	F9 full gene sequence	22,505	$13,477,164
81339	MPL gene seq alys exon 10	21,996	$4,072,837
81223	CFTR gene full sequence	20,508	$10,229,517
0037U	Trgt gen seq DNA 324 genes	17,705	$61,967,500
81270	JAK2 gene	17,619	$1,614,976
81450	HL neo 5-50DNA/DNA&RNA	17,249	$13,035,022
81256	HFE gene	16,985	$1,109,174
0242U	Trgt gen seq alys pnl 55-74	16,305	$81,525,000
81374	HLA I typing 1 antigen LR	14,659	$1,083,420
81542	Oncology prostate mRNA 22 cnt gen	13,771	$53,331,280
81226	CYP2D6 gene common variants	10,992	$4,928,325
81225	CYP2C19 gene common variants	10,897	$3,167,717
81207	BCR/ABL1 gene minor bp	10,518	$1,520,652
81219	CALR gene com variants	9,737	$1,183,753
81595	Cardiology heart transplant mRNA	9,709	$31,457,160
81305	Myd88 gene p.leu265pro vrnt	9,114	$1,598,351
0005U	Oncology prst8 3 gene ur algorithm	8,480	$6,444,546
81546	Oncology thyroid mRNA 10,196 gen alg	8,417	$30,301,200
81334	Runx1 gene targeted seq analysis	8,305	$2,736,261
	Total top 25 codes targeted by UHC for Z-codes	**594,489**	**$981,548,300**
	Total all 237 codes targeted by UHC for Z-codes	**724,691**	**$1,250,713,249**

Source: CodeMap and CMS

NeoGenomics, Quest and Labcorp at J.P. Morgan Healthcare Conference

The top executives at NeoGenomics, Quest Diagnostics and Labcorp participated in Q&A sessions at the J.P. Morgan Healthcare Conference held in San Francisco on January 8-11. Here are some highlights.

NeoGenomics (Fort Myers, FL) is focusing its R&D on tests for cancer therapy selection and minimum residual disease (MRD), according to Chief Executive **Chris Smith**. He estimates that therapy selection is potentially a $9 billion testing market that is only penetrated 20%. MRD is potentially a $20 billion testing market that is severely underpenetrated at only around 5%. Therapy selection and MRD have compound annual growth rates of ~15% and greater than 25%, respectively.

The U.S. District Court for the Middle of North Carolina issued a preliminary injunction against NeoGenomics in late December. The order is part of Natera's ongoing patent infringement lawsuit against NeoGenomics. It forbids NeoGenomics from marketing its RaDaR MRD assay. Smith said NeoGenomics will appeal the ruling noting that "we feel really good about our legal position."

Smith also said that FDA regulation of LDTs will "probably ultimately become a reality." He said that NeoGenomics is putting its MRD and next-gen sequencing tests under design control in anticipation of FDA regulation.

"We think there is an upside to companies in front of this…. For example, one of our biggest challenges is hospitals wanting to internalize NGS testing. It's one thing if you're MD Anderson or Sloan Kettering, it's another thing if your Paducah Hospital. Do you really want the FDA walking into your lab and doing a site inspection? So, the companies that move quickly and are prepared [for LDT regulation] are going to come out ahead."

Jim Davis, President & CEO of **Quest Diagnostics**, highlighted his company's acquisition of NewYork-Presbyterian's outreach lab business for $275 million early last year. "When you see an institution like that decide to get out of the outreach business, I think it makes a statement to the rest of the industry…. Certainly they did not exit the business because they were losing money on their outreach business."

However, Davis noted that when NewYork-Presbyterian CEO Stephen Corwin, MD, was "faced with investment priorities from neurosurgery, from cancer, from women's healthcare, from cardiovascular work, in an era when the cost of capital is significantly higher than it was five years ago, he'd rather pour his money into things that really drive market share away from the institutions he's competing with."

"If hospitals have to make a choice of [where to invest capital], they are going to put it into surgery instead of lab," said **Labcorp** Chairman and CEO **Adam Schechter**. The number one issue that a hospital thinks about when considering a deal is "Will our physicians be upset based on their ability to get test results for their patients when they want them…. We've been able to show time and time again that we know how to do this, and we can do it well."

Meanwhile, Schechter said that "The payers have seen the impact of us having a lot of these hospital deals. When you do a hospital deal, the price of the tests in the hospital comes down immediately and the payers benefit from that. And therefore, we have been able to show the payers the benefit and say that we should be able to partake in a little bit of that benefit [savings]."

LDTs are about 5% of Labcorp's overall test volume. "What they're [FDA] trying to do is take legislation that was specific to the device industry and apply to an entirely different focus." Schechter said that any FDA regulation should be developed specifically for LDTs, such as the VALID Act.

On direct-to-consumer testing, Schechter said Labcorp is ready for it, but "It's just not a significant amount of our business today and it's hard to tell how fast it will scale up."

Lab Stocks Fell 8% In 2023

Twenty-five lab stocks fell by an unweighted average of 8% in 2023. Overall, 10 lab stocks rose and 15 fell. The top-performing lab stock in 2023 was NeoGenomics, up 75%. Labcorp was up by 12% and Quest Diagnostics was down by 12%. In comparison, the S&P 500 Index rose by 24% last year.

Company (ticker)	Stock Price 12/29/23	Stock Price 12/30/22	2023 Price Change	Enterprise Value ($ millions)	Revenue for Trailing 12 mos. ($ millions)	Enterprise Value/ Revenue
NeoGenomics (NEO)	$16.18	$9.24	75%	$2,270	$575	3.9
Natera (NTRA)	62.64	40.17	56%	7,030	989	7.1
Exact Sciences (EXAS)	73.98	49.51	49%	15,220	2,406	6.3
Myriad Genetics (MYGN)	19.14	14.51	32%	1,810	734	2.5
Opko Health (OPK)	1.51	1.25	21%	1,340	867	1.5
Veracyte (VCYT)	27.51	23.73	16%	1,820	343	5.3
Labcorp (LH)	227.29	202.30	12%	25,010	15,071	1.7
Sonic Healthcare (SHL.AX)*	32.08	29.97	7%	17,600	8,170	2.2
CareDx (CDNA)	12.00	11.41	5%	415	297	1.4
Interpace Biosciences (IDXG)	1.08	1.04	4%	60	38	1.6
Guardant Health (GH)	27.05	27.20	-1%	3,490	536	6.5
DermTech Inc. (DMTK)	1.75	1.77	-1%	47	14	3.3
Enzo Biochem (ENZ)	1.39	1.43	-3%	8	32	0.3
Fulgent Genetics (FLGT)	28.91	29.78	-3%	28	286	0.1
Castle Biosciences (CSTL)	21.58	23.54	-8%	366	192	1.9
Quest Diagnostics (DGX)	137.88	156.44	-12%	20,390	9,297	2.2
Exagen (XGN)	1.99	2.40	-17%	31	52	0.6
Aspira Women's Hlth (AWH)	4.08	4.95	-18%	39	9	4.3
Biodesix (BDSX)	1.84	2.30	-20%	198	44	4.5
Psychemedics (PMD)	2.96	4.90	-40%	18	23	0.8
ProPhase Labs (PRPH)	4.52	9.63	-53%	96	63	1.5
23andMe (ME)	0.91	2.16	-58%	262	270	1.0
Invitae (NVTA)	0.63	1.86	-66%	1,430	482	3.0
GeneDx (WGS)	2.75	8.71	-68%	31	207	0.1
Biocept (BIOCQ)	0.04	15.90	-100%	5.1	1.4	3.6
Totals & Averages			**-8%**	**$99,015**	**$40,998**	**2.4**

*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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