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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

FDA Finalizes LDT Regulation; Partial "Grandfather" Exemptions for Existing LDTs

Although less severe than the FDA's initial proposed regulations, the Final Rule (published May 6) will add a new complex layer of bureaucracy for labs offering laboratory-developed tests (LDTs). LDTs on the market prior to May 6 will not have to go through the full FDA application and clearance process. However, labs will need to develop quality system complaint files, registration, labeling, etc. for each LDT they currently offer. New LDTs will ultimately need to go through the full FDA application and clearance process. *Detailed coverage and expert analysis on pages 3-5.*

Lawsuit Likely, But No Slam Dunk

The American Clinical Laboratory Assn. (ACLA) is expected to soon file a lawsuit seeking an injunction to stop the FDA from implementing its new LDT regulations. But suing the government is never easy and the FDA cleverly crafted its Final Rule to lower the risk of an injunction. For expert legal opinion from Nathan Brown, Partner at Akin Gump (Washington, DC), *see page 4.*

How Much Will New FDA Regs Cost Your Lab?

Small hospital and independent labs that want to keep their existing LDTs on the market should expect to budget 1-2 FTEs to focus on meeting the new FDA Final Rule, according to Christine Bump, a regulatory attorney at Penn Avenue Law & Policy (Washington, DC). Larger labs offering 50 or more LDTs may need to devote up to 4-5 FTEs to the effort. *Continued on page 5.*

Quest to Buy PathAI Lab to Speed Move to Digital Pathology & AI

Under an agreement announced May 1, Quest Diagnostics will buy out PathAI's diagnostics lab in Memphis. It will then turn this lab into a digital pathology and AI center to help support Quest's pathology businesses in the United States and overseas. The purchase price has not yet been revealed. The deal is expected to be completed by June 30. For a summary of our exclusive interview with Quest's Senior Vice President of Oncology Kristie Dolan, *see page 2.*

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QUEST TO BUY PATHAI LAB TO RAMP UP DIGITAL PATHOLOGY & AI (*cont'd from p. 1*)
PathAI (Boston), which was founded by its CEO Andy Beck, MD, PhD in 2016, has developed a digital pathology image management system (branded AISight) and various AI algorithms for analyzing slide images. The company has raised a total of $255 million from more than 20 outside investors including Labcorp, Kaiser Permanente, Merck and Bristol Meyers.

PathAI originally acquired the Memphis laboratory through its acquisition of Poplar Healthcare in July 2021 (see *LE*, August 2021, pp. 1&4). This lab currently has roughly 300-350 employees, including 20 pathologists. Its specialty divisions include GI Pathology, Bostwick Laboratory (uropathology), D-Path Dermatopathology and Women's Health Labs.

Over the past three years, PathAI worked to accelerate the transition to digital pathology at the Memphis lab, which currently digitizes the majority of its pathology slides. PathAI also installed its digital image management system at the Memphis lab and began applying its AI algorithms to certain slide images, including its AI-based algorithm for NASH scoring for chronic liver disease.

PathAI is keeping its AISight and AI-based businesses. The company is also keeping its biopharma lab in Memphis, which provides end-to-end clinical trials services.


Kristie Dolan

In total, Quest has approximately 400 board-certified pathologists nationwide, including about 100 dermatopathologists. Dolan says that Quest has already been transitioning to digital pathology at its AmeriPath labs in Denver (14 pathologists) and Tampa (26 pathologists), as well as at its regional lab in Clifton (northern New Jersey). Dolan says that the acquired Memphis lab will help speed Quest's transition to digital pathology by serving as a national hub for digitizing slides and applying AI. Quest also plans to utilize PathAI's AISight for image management under a long-term license agreement.

Jim Sweeney is President of Diagnostics at PathAI and has been in charge of the Memphis lab since 2014. Dolan says that the new management structure hasn't been finalized yet. However, she says that Quest plans to hire the majority of current employees at the Memphis lab.

Quest Diagnostics will utilize digital pathology for:

- Quest's labs in Denver, Tampa and northern New Jersey will continue with their ongoing transition to digital pathology. The Memphis lab will serve as a slide-scanning hub and image manager for Quest's other pathology lab locations. Over time, tissue specimens will be sent to the Memphis lab for scanning. Digitized images can then be sent to Quest/AmeriPath pathologists around the country for interpretation.
- Quest is also planning to use digital pathology to support hospital-based pathology departments. Hospitals can refer slide prep and digitization to the Memphis lab, while continuing to perform professional interpretations in-house.
- Digital pathology will also make Quest/AmeriPath's pathologist expertise more readily available to international clients experiencing a shortage of pathologists. In this scenario, the foreign lab would handle the slide prep and digitization. Quest/AmeriPath's pathologists will perform digital reads for both primary diagnosis and second opinions.

Quest has also licensed access to PathAI's software tools for helping pathologists read digitized slide images. Dolan anticipates that the first AI-based tools that Quest will adopt will focus on prostate and breast cancer cases.

How the FDA Final Rule Treats "Grandfathered" LDTs

Jonathan Genzen, MD, PhD, Chief Medical Officer and Senior Director of Governmental Affairs at ARUP Laboratories (Salt Lake City, UT), has been closely following the FDA's movement toward regulating laboratory-developed tests. Below we summarize Dr. Genzen's perspectives on the Final Rule with an emphasis on what it means for currently marketed LDTs.

What are the Stage 1 requirements for "grandfathered" LDTs under the Final Rule?
These tests are not fully "grandfathered" under the Final Rule, as certain FDA oversight requirements still apply.


Jonathan Genzen, MD, PhD

Currently marketed LDTs (on the market prior to May 6, 2024) will need to comply with FDA Medical Device Reporting (MDR) regulations. This includes reporting certain device-related adverse events and product problems to the FDA, as well as correction and removal reporting requirements.

Currently marketed LDTs will also need to comply with one of the Stage 3 quality system requirements (Complaint Files — 21 C.F.R. 820.198). Laboratories will be required to establish and maintain procedures for receiving, reviewing, and evaluating complaints for their LDTs.

The Stage 1 requirements will need to be met by May 6, 2025.

What are the Stage 2 requirements for "grandfathered" LDTs under the Final Rule?
Currently marketed LDTs will need to comply with FDA registration, listing, labeling, and investigational use requirements by May 6, 2026. The most complex of these requirements is labeling. It appears that all LDTs eligible under the currently marketed enforcement discretion policy will need to meet full FDA labeling requirements for IVDs. This will be a complex task to conduct retrospectively, as labeling requirements are extensive and will need to be completed within two years to remain in compliance with the Final Rule.
(https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=809.10).

Which anatomic pathology services are covered under the Final Rule for LDTs?
From my interpretation, with the exception of manual staining and manual immunohistochemistry ("1976-type" LDTs), the Final Rule doesn't distinguish between AP and CP testing. The Final Rule appears to apply to all LDTs, with the exception of manual interpretation of the final slides by a pathologist. This means that currently performed anatomic pathology LDTs, including non-manual IHC staining, are now subject to FDA oversight.

What happens when an existing LDT is modified?
The moment a currently marketed test has a modification considered to be significant by the FDA (and they provide representative examples in the Final Rule), then the LDT would be subject to additional QS requirements including design controls, purchasing controls, acceptance activities, corrective and preventive action (CAPA), and records requirements. Such modifications to existing LDTs will also require a premarket submission to the FDA.

Over time, I anticipate that many routine test modifications, including sample type changes and automation of manual assays on liquid handlers, will now necessitate FDA submissions. And I suspect that the FDA is underestimating the number of tests that will ultimately need to go through premarket review, as well as the financial impact to the clinical laboratory community.

Is the NYS CLEP less expensive and a quicker process than FDA review?
I believe that LDT submission and review under the NYS Clinical Laboratory Evaluation Program (CLEP) – which oversees clinical laboratory testing for NY patients – is available only

to NYS-accredited labs. NY clinical laboratory accreditation is likely not a practical option for most laboratories that do not intend to perform testing on NY patients. The NY CLEP performs outstanding, high-quality work, and they will need to share their perspective on how the program should or should not be used in the context of the FDA's Final Rule.

Is a lawsuit challenging FDA's authority to regulate LDTs likely?
I believe that litigation is very likely. The FDA's language in the Final Rule regarding "illegality" (page 30) makes this even more likely in my opinion. If not following the FDA's new framework for LDTs is deemed illegal—even if it compromises the ability to care for patients (e.g. emergency validations for clinically urgent testing in acute settings) – then the lab industry has been backed into a corner and judicial review could be the only remaining remedy.

Overview of Test Types and New FDA Regulations

*Stage 1: May 6, 2025**	*Stage 2: May 6, 2026**	*Stage 3: May 6, 2027*	*Stage 4: November 6, 2027*	*Stage 5: May 6, 2027*
Postmarket reporting requirements (e.g., MDR reporting, corrections & removals reporting) and Quality System complaint file requirements. *"Grandfathered" LDTs must comply.	Registration & class-based listing, labeling & investigational use. *"Grandfathered" LDTs must comply.	Full Quality System requirements in effect unless specifically addressed by FDA in the Final Rule Preamble.	Premarket application (PMA) submissions required for "high-risk" LDTs.	FDA submissions required for "moderate-risk" LDTs.

LEGAL CHALLENGE LIKELY TO BE FILED SOON (*cont'd from page 1*)

A lawsuit challenging the FDA's Final Rule and seeking emergency injunctive relief is very likely, according to Nathan Brown, an attorney specializing in FDA regulations at Akin Gump (Washington, DC).


Nathan Brown

Brown says that comments on the rule indicate the legal arguments will include: (1) lack of statutory authority on the theory that LDTs fall outside the FDCA's definition of devices; and (2) lack of clear statutory authority to regulate on an issue of major national significance (i.e., the major questions doctrine). Challengers might also argue that the FDA failed to adequately estimate and account for the burdens and costs of the rule; that the rule violates the First Amendment; and that the rule infringes upon the practice of medicine.

Any potential lawsuit would likely be filed in a friendly court such as the Fifth Circuit in New Orleans, which has a reputation as being one of the most conservative courts in the country, notes Brown.

A motion for emergency injunctive relief would be decided relatively quickly. A ruling either granting or denying such a motion would be immediately appealable, and (in the event of an initial refusal to enjoin the Final Rule) a court could suspend the rule's effective date until the appeal is decided.

However, Brown says that the Final Rule's partial "grandfathering" of existing LDTs and its phased-in regulations over four years make the argument for emergency injunctive relief difficult.

There is also potential for an entity or group that supports the Final Rule to file suit, and seek emergency injunctive relief, in an effort to ensure that the rule continues in force, according to Brown.

HOW MUCH WILL NEW FDA REGS COST YOUR LAB? (*cont'd from p. 1*)
In addition to or in lieu of FTEs, Bump says that labs may need to retain outside counsel or consultants to help develop and implement systems and prepare documents necessary for compliance.

The best consultants are former FDA reviewers and can cost between $100 and $200 per hour, according to Bump.

Labs can expect to pay between $300 and $600 per hour for legal advice from a small law firm and $800 to $1,000 per hour from bigger firms. The key here is that your lawyer has had experience dealing with the FDA, notes Bump.


Christine Bump

"Lab directors know the CLIA regulations and CAP accreditation standards like the back of their hand. However, FDA processes and communication are a whole new world," says Bump.

Bump says that it could take several years for an industry lawsuit and/or potential legislative changes (i.e., reintroduction of the VALID Act) to play out. In the meantime, labs must start planning to comply with Stage I & II of the FDA's Final Rule.

Failure to follow the Final Rule could result in FDA letters, inspections, and potential suspension of noncompliant LDTs. In extreme instances, the FDA has also shut down facilities and fined companies and their executives.

Publicly Traded 23andMe Could Go Private

CEO and co-founder Anne Wojcicki is making plans to acquire all the outstanding shares of 23andMe (South San Francisco, CA) that she does not already own, according to an SEC filing made on April 17. Wojcicki currently owns 20% of the company's shares accounting for 50% of the voting power. It was also indicated in the filing that 23andMe is to stay under Wojcicki's control and will not be willing to support alternative transactions.

The Board at 23andMe's recently formed a special committee to review alternatives and maximize shareholder value. 23andMe says that the special committee will be reviewing Wojcicki's proposal, but will ultimately move forward with what they view as the best interests of the company.

23andMe specializes in direct-to-consumer DNA testing for genetic ancestry and consumer health. It is also trying to utilize its massive DNA database to discover new pharmaceuticals.

23andMe has accumulated a total of $2 billion in losses since being formed in 2006. In its latest reported fiscal year ended March 31, 2023, the company reported a net loss of $312 million on revenue of $299 million.

Revenue and Losses at 23andMe ($000)*

	2023	2022	2021	2020	3 Year CAGR
Revenue	$299,489	$271,893	$243,920	$305,463	-0.7%
Research and development expense	222,596	189,377	159,856	181,276	7.1%
Sales and marketing expense	119,927	100,338	43,197	110,519	2.8%
General and administrative expense	115,984	97,383	99,149	59,392	25.0%
Loss From Operations	-324,011	-254,153	-185,196	-258,447	NA
Net Loss	-311,656	-217,490	-183,619	-250,863	NA

*Fiscal year ends March 31 Source: *Laboratory Economics* from 23andMe 10-K annual reports

Accumen's Strategies for Reference Test Contracting

Most health systems and their labs remain under financial pressure due to rising employee costs and inflation. As a result, they are looking to cut costs anywhere they can, including reference (aka send-out) testing expenses. The lab consulting firm Accumen Inc. (Scottsdale, AZ) negotiates about 15-20 reference lab agreements per year for health systems and hospitals. Below we summarize strategies for negotiating your lab's next reference testing contract from Accumen's Brent Bolton, VP/GM, Supply Chain & Lab Stewardship.

Brent Bolton

What is the average percentage of hospital lab budget spent on reference testing?
Lab department costs average about 4% of the total hospital operating cost budget. And about 30% of the lab budget is spent on lab supplies. Reference testing is around 20% of overall lab supplies cost. So, reference testing represents an average of roughly 6% of the hospital lab budget and less than 1% of the average hospital's total expenses.

Who else besides ARUP, Labcorp, Mayo and Quest should an RFP go to?
Depending on where the hospital lab is located, it may also want to consider regional labs. A few examples include Wisconsin Diagnostic Labs (WDL), TriCore, Sonic Healthcare, BioReference and Cleveland Clinic.

In addition, it's good to get pricing from some of the secondary/specialty labs that focus on esoteric testing, toxicology testing and other labs that do third-party testing. Some specialty tests will be lower-cost and have a quicker turnaround time when ordered directly from a secondary lab like NeoGenomics. As a result, it often makes sense to carve out certain specialty tests from the primary reference lab agreement.

What length of term should a new reference testing contract be?
Three years is generally the average reference lab contract duration. Five years is okay if you can get significant discounts. There should never be volume commitments with the reference lab agreement; it should be a fee schedule only with fixed pricing. Auto renewals are also acceptable as long as there is pricing protection.

How many tests should be included in an RFP?
All your send-out tests should be included. This might result in an RFP with 1,000+ tests.

What about new esoteric tests that are introduced after a reference testing contract is signed?
Labs must consistently monitor and manage send-out testing to ensure new expensive testing does not fall through the cracks. For any tests with significant volume or high pricing, request multiple bids to compare with the primary reference lab pricing even after the primary reference lab agreement is signed. Many of the reference labs will allow for annual pricing reviews on the testing that was not included in the original RFP, especially if this new testing is increasing volumes and revenues to the reference lab. If the agreement is done well, this new testing can help to get rebates or volume discounts which will minimize the overall cost increase exposure.

What are some tips to help make sure that hospitals don't overpay for reference testing?
Conducting an RFP with multiple reference labs that are legitimate options will help ensure hospitals are not overpaying for reference testing.

One cost that can sneak up on a hospital lab is miscellaneous testing. The physician may choose to send testing to the primary reference lab but specify that it is performed at a specialty lab (commonly known as a pass through). The primary reference will then mark up that testing and also charge handling fees. It will be reported on the hospital lab's bill as a miscellaneous test. Hospital labs need to monitor these miscellaneous testing codes, descriptions and fees and see if that testing can be performed at the primary reference lab instead.

Could pricing for reference tests simply be set at a percentage of the Medicare CLFS rates?
Yes, it is possible, but the reference labs will never willingly change to this transparent pricing model on all testing without federal regulatory enforcement. Reference labs commonly set pricing based on several factors including total revenue projections and test volumes; and not necessarily on a test-by-test basis. As a result, the biggest determinant to pricing is the amount of reference lab competition available to each hospital lab client.

What are your thoughts on using benchmarking pricing in the RFP process?
Most benchmark pricing is just averages on top of other averages, and the data is often outdated. It generally does not account for market changes, rebates, or the hidden value adds that a vendor can provide. A health system may feel they are getting a good deal — even when they are not. The only truly accurate benchmark pricing comes from utilizing a third party (e.g., Accumen) that sees real time national market data from every reference lab, every GPO, and every size hospital.

Can you provide average pricing data on some commonly referred tests?
Average pricing per test is extremely subjective, as it is based on the performing testing lab and location, but most notably the pricing is based on the per test volumes sent to the reference lab. It is more important to look at the total cost of aggregated reference lab testing costs versus focusing on individual test codes, unless, of course, there are significant pricing outliers. Pricing for testing can range significantly given the variables I've mentioned. For example, a chlamydia trachomatis/neisseria gonorrhoeae (CT/NG) amplified probe can range anywhere from $15-$40.

What kind of savings can hospitals expect when sending out an RFP for reference testing?
Savings are dependent on each situation and each hospital lab's level of leverage. As I mentioned earlier, true competition is the best driver for aggressive savings (and that's more than just sending out RFP's). That said, we generally see savings of 10%+ for contract renewals with an incumbent reference lab and up to 25% if a reference lab vendor change is made (which can be a heavy lift for the hospital as it involves a lot of scarce IT resources).

What makes the IT transition to a new reference lab so difficult?
It's difficult because health system IT resources are generally constrained, thereby creating a bottleneck. Every individual send-out test has to be built into the LIS, and there could be thousands of tests that the health system or hospital sends to the new primary reference lab. Each one of those tests will have a test code, description, reference range for each result, specimen collection information, etc. that needs to be added to ensure test orders and results are entered accurately.

Will FDA regulation of LDTs cause hospitals to send out more tests to reference labs?
Under the FDA's initial proposed regulations, we thought the outcome was going to be catastrophic for some hospital labs. They would have had to send out all of their LDT testing to one of the national reference labs. With the final FDA ruling, there appears to be a lot more flexibility. It looks like hospitals will be exempt from having to file premarket applications with the FDA for their existing LDTs.

Can't hospitals simply take advantage of reference testing contracts through their GPO?
Yes. Hospitals can always utilize the GPO pricing tiers that they qualify for, and that will prevent them from overpaying on reference lab testing. But to maximize savings, value adds, and create favorable contract terms, the best way is to create an agreement between the hospital and the reference lab with a fee schedule that is custom tailored for the hospital. As mentioned earlier, the best way to do that is to have a competitive bidding process that looks at each hospital's unique test mix, volumes, service level requirements, and consolidation/standardization opportunities. The GPO contract will not take all those particulars into account. It's also worth noting that a reference lab fee schedule is one of the most important agreements that a hospital can negotiate, so it's always worth the effort to do so.

Spotlight Interview with GoPath CEO Jim Lu, MD, PhD

GoPath Diagnostics (Buffalo Grove, IL) was founded in 2012 by its Chief Executive and Medical Director Jim Lu, MD, PhD. The full-service pathology lab now operates a 30,000-square-foot laboratory and office just outside of Chicago as well as a smaller lab in Scottsdale, Arizona. GoPath currently has 120 employees, including four full-time and two part-time pathologists. Here's a summary of our recent interview with Dr. Lu.

Jim Lu, MD, PhD

Describe your background and why you started GoPath?
I completed my residency and fellowship training in GI/Liver and transplant pathology at the University of Pittsburgh Medical Center (UPMC). During my time at UPMC (2000-2004), I was exposed to the first generation of digital pathology systems. I then worked at Quest's AmeriPath division in Indianapolis for eight years. I left AmeriPath to form GoPath in 2012 with the intent of creating a digital-pathology-focused independent lab. Myself and four pathologist-investors contributed a combined $500,000 in funding to get GoPath off the ground.

How has your adoption of digital pathology occurred?
We installed our first whole-slide scanner (Leica Aperio AT2) in 2016. Over time, we have shifted to less expensive scanners made by KFBIO (Zhejiang, China), which has the biggest market share for digital pathology scanners in China—installed at more than 2,000 hospitals.

GoPath is now digitizing nearly 100% of its surgical biopsy slides. We are totally digital for GI, GU, general surgical and cytology, which cover most of our business. It is still a challenge to view hematopathology blood or bone marrow smears due to the nature of slides and limited resolution due to scanner capability. Last year, we processed 18,000 slides and we're on track to process between 25,000 and 30,000 slides this year.

Is the use of digital pathology greater in China?
It's hard to say for sure. But China is adopting digital pathology quickly because of availability of affordable scanners early on and demand for digital consultation due to limited experts. A high volume of cases is another reason to push to digital, so that AI can be applied. Many hospitals in China are now using digital scanning and AI to screen cervical pap smears.

How is GoPath benefitting from digital pathology?
Among other things, Digital pathology is allowing GoPath to expand into new subspecialty areas by connecting with off-site pathologists for digital interpretations.

How does GoPath manage its slide images?
We've internally developed our own LIS with an integrated digital pathology management system. We're also marketing this system, branded DigitCells, to outside pathology labs and hospitals.

Have you had any luck in getting private health insurers to reimburse for digitizing slides?
We are submitting the new add-on CPT codes for every digital case; some insurers pay, and some do not. More importantly, digital pathology improves our workflow and efficiency.

Any plans to add AI tools?
Yes. GoPath recently signed an agreement with Nucleai (Chicago) to develop new AI tools for clinical research and diagnostics. Nucleai's AI technology utilizes spatial biomarker analysis that, for example, analyzes the relationship between tumor cells and the surrounding stroma (i.e., non-cancer cell and non-immune cell components of a tumor). The partnership will initially focus on developing AI tools that help predict the course of prostate, bladder and breast cancers.

Labcorp to Buy Sonic's California Clinical Lab Business

On April 17, Sonic Healthcare announced it was selling its clinical lab testing business in California (dba WestPac Labs) to Labcorp for an undisclosed amount. The transaction is expected to close in the next few months.

Sonic's WestPac Labs includes three California laboratories:

- West Pacific Medical Laboratory (Santa Fe Springs). Acquired by Sonic in 2017.
- Central Coast Pathology (San Luis Obispo). Acquired by Sonic in 2011.
- Physician's Automated Laboratory (Bakersfield). Acquired by Sonic in 2010.

Sonic is exiting the clinical lab business in California. However, Sonic is expected to continue to provide anatomic pathology services in California.

Labcorp already operates a major laboratory in San Diego.

Haverford Healthcare (Radnor, PA) advised Sonic on the transaction.

Labcorp to Acquire Invitae's Assets for $239 Million

Labcorp's $239 million cash offer has been declared the winning bid in the bankruptcy court-supervised sale of most of Invitae's assets. The transaction is expected to close by September 30.

Labcorp expects the deal to bring about $275 million to $300 million in annual revenue. Invitae reported revenue of $487 million and a cash burn rate of $365 million in 2023 (see *LE*, March 2024, p. 9). Labcorp believes it can make the Invitae business profitable within the first year by cutting marketing and administrative expenses.

The acquired Invitae assets will include its hereditary cancer testing business, women's health and rare disease testing.

Invitae filed for Chapter 11 bankruptcy protection in the U.S. Bankruptcy Court for the District of New Jersey on February 13, 2024. Invitae has accumulated losses totaling more than $6 billion since its inception in 2013 (see *LE*, February 2024, p. 10).

Mountain View Hospital Buys Local Pathology Group

Mountain View Hospital (Idaho Falls, ID) has purchased select assets of Pathology Associates of Idaho Falls (PAIF) effective March 31.

Headquartered in Idaho Falls and incorporated in 1970, PAIF is a hospital-based anatomic pathology group with five pathologists. PAIF provides professional services to multiple hospitals in Eastern Idaho, including Mountain View Hospital, which recently opened a new technical laboratory.

Haverford Healthcare advised PAIF on the sale.

Correction: The April 2024 issue of *Laboratory Economics* mistakenly reported that Paul Beyer was the current President of Ascend Clinical LLC (Sunnyvale, CA). In fact, Mr. Beyer is not the current President of Ascend Clinical – he left Ascend in September 2023. Ascend was acquired by Eurofins Scientific in April 2024.

Public Lab CEOs Paid Average of $5.7 Million in 2023

The top executives at 22 publicly traded lab companies were paid an average of $5.7 million each last year, according to shareholder proxy statements. Altogether, the 22 executives earned a total of $125 million, including $91 million from stock and option awards.

The highest paid lab executive was **Kevin Conroy**, 58, Chairman and CEO of **Exact Sciences** (Madison, WI). Conroy received a total compensation of $16.1 million, including a salary of $1 million, $1.9 million from non-equity incentives, and just under $13 million from stock awards. Exact Sciences reported a net loss of $204 million on revenue of $2.5 billion in 2023.

The next highest paid executive was **Adam Schechter**, 59, at **Labcorp** (Burlington, NC). Schechter received a salary of $1.4 million, $11.3 million from stock and option awards, $2.3 million from bonus and incentives and $938,253 from all other compensation for a total pay package of just under $16 million. Labcorp reported net income of $418 million in 2023, down from $1.3 billion in 2022; revenue increased 2.5% to $12.2 billion.

Steve Chapman, 45, President and CEO at **Natera Inc.** (Austin, TX) earned a total of $12.7 million, including salary of $751,052, bonus and incentives of $833,793 and stock and option awards of $11.1 million. Natera reported a net loss of $435 million on revenue of $1.1 billion in 2023.

James Davis, 61, Chairman and CEO of **Quest Diagnostics** (Secaucus, NJ) earned a total of $12.7 million. Davis received a salary of $1.2 million, stock and option awards totaling $9.8 million, $1.4 million from non-equity incentives, and $346,710 in other compensation. Quest reported net income of $854 million on revenue of $9.3 billion in 2023.

The lowest paid lab exec was **Helmy Eltoukhy**, 45, Chairman and Co-Chief Executive Officer of **Guardant Health** (Palo Alto, CA) who received $11,591 in total compensation. Guardant Health reported a net loss of $479 million on revenue of $564 million in 2023.

$87K Average Employee Compensation

Data from six of the largest publicly traded lab companies shows they paid their median employees an average of $87,432 each in 2023. Employee compensation has seen an average 6.9% increase per year between 2018-2023. The highest paid median employees belong to Exact Sciences, whose median employee earned $145,325, followed by Myriad Genetics at $116,418. Labcorp paid its median employee $61,201 in 2023 and Quest Diagnostics' median employee took home $68,163.

Median Employee Compensation at Six Big Labs

Company	2023	2022	2021	2020	2019	2018	5-Yr CAGR
Labcorp	$61,201	$56,191	$57,614	$41,670	$41,834	$43,230	7.2%
Quest Diagnostics	68,163	63,854	67,206	71,645	53,492	46,749	7.8%
Exact Sciences	145,325	135,992	128,893	110,616	113,869	98,783	8.0%
Opko Health	44,158	43,798	41,879	42,848	41,445	38,661	2.7%
Myriad Genetics	116,418	89,911	74,021	89,031	77,814	77,814	8.4%
NeoGenomics	89,324	82,000	74,000	76,844	74,903	70,258	4.9%
Averages for 6 lab cos.	$87,432	$78,624	$73,936	$72,109	$67,226	$62,583	6.9%

Source: *Laboratory Economics* from company proxy statements

2023 Public Laboratory CEO Compensation

Company/Executive	Salary	Bonus & Incentives	Value of Stock & Option Awards	Other Comp*	Total Compensation
Aspira Women's Health					
Nicole Sandford, 53, President & CEO	$500,000	$112,500	$392,074	$31,016	$1,035,590
Biodesix					
Scott Hutton, 52, President & CEO	515,000	98,058	1,675,623	1,865	2,290,546
CareDx Inc.					
Reginald Seeto, 52, Former President & CEO	556,813	0	8,536,615	1,458,325	10,551,753
Castle Biosciences					
Derek J. Maetzold, 62, President & CEO	686,400	893,350	0	26,234	1,605,984
DermTech Inc.					
Bret Christensen, 53, President and CEO	388,846	311,076	955,000	60,180	1,715,102
Enzo BioChem					
Hamid Erfanian, 54, Former CEO	615,877	1,502,488	518,000	27,827	2,664,192
Exact Sciences					
Kevin Conroy, 58, Chairman & CEO	1,041,700	1,920,277	12,976,236	181,686	16,119,899
Exagen					
John Aballi, 39, President and CEO	525,000	393,750	0	13,200	931,950
Fulgent Genetics					
Ming Hsieh, 68, Chairman & CEO	1,000,000	1,309,167	3,000,000	0	5,309,167
GeneDx					
Katherine Stueland, 48, CEO & Director	675,000	0	2,829,420	70,915	3,575,335
Guardant Health					
Helmy Eltoukhy, PhD, 45, Chairman & Co-CEO	1	0	0	11,590	11,591
Interpace Biosciences					
Thomas W. Burnell, 62, President & CEO	435,625	226,525	0	16,257	678,407
Labcorp					
Adam Schechter, 59, Chairman & CEO	1,373,692	2,346,018	11,321,392	938,253	15,979,355
Myriad Genetics					
Paul Diaz, 62, President & CEO	1,086,750	1,168,440	9,796,451	56,718	12,108,359
Natera Inc.					
Steve Chapman, 45, President & CEO	751,052	833,793	11,133,142	9,900	12,727,887
NeoGenomics					
Christopher Smith, 61, CEO & Director	1,000,000	1,850,000	8,803,638	12,308	11,665,946
Opko Health Inc.					
Phillip Frost, MD, 87, Chairman & CEO	960,000	480,000	824,000	13,200	2,277,200
ProPhase Labs					
Ted Karkus, 64, Chairman & CEO	675,000	200,000	2,465,000	27,200	3,367,200
Psychemedics					
Brian Hullinger, 57, President & CEO	125,558	25,000	612,000	0	762,558
Quest Diagnostics					
James E. Davis, 61, Chairman & CEO	1,175,000	1,361,531	9,790,593	346,710	12,673,834
Veracyte Inc.					
Marc Stapley, 54, CEO & Director	650,000	900,250	5,631,384	3,000	7,184,634
23andMe					
Anne Wojcicki, 49, Chairman & CEO	62,920	0	0	0	62,920
Totals, 22 executives	$14,800,234	$15,932,313	$91,260,568	$3,306,384	$125,299,499
Averages, 22 executives	$672,738	$724,196	$4,148,208	$150,290	$5,695,432

*Other compensation includes reimbursement for financial planning services, car allowance, personal liability insurance premiums, executive physical exams, home security systems, country club memberships, personal use of company jets and other perks.
Source: *Laboratory Economics* from company proxy statements

Lab Stocks Up 18% Year-to-Date In 2024

Twenty-four lab stocks have risen 18% year to date through May 13. In comparison, the S&P 500 index is up 10% year to date. The top-performing stocks YTD are GeneDx (WGS), up 750%; Natera (NTRA), up 65%; and Interpace Biosciences (IDXG), up 36%. Labcorp (LH) is down 7% and Quest Diagnostics (DGX) is up 2% year to date.

Company (ticker)	Stock Price 5/13/24	Stock Price 12/29/23	2024 Price Change	Enterprise Value ($ millions)	Revenue for Trailing 12 mos. ($ millions)	Enterprise Value/ Revenue
GeneDx (WGS)	$23.38	$2.75	750%	$548	$222	2.5
Natera (NTRA)	103.33	62.64	65%	12,490	1,209	10.3
Interpace Biosciences (IDXG)	1.47	1.08	36%	60	41	1.5
Myriad Genetics (MYGN)	24.93	19.14	30%	2,350	774	3.0
CareDx (CDNA)	14.98	12.00	25%	589	275	2.1
ProPhase Labs (PRPH)	5.14	4.52	14%	113	29	3.9
Castle Biosciences (CSTL)	24.25	21.58	12%	455	251	1.8
Quest Diagnostics (DGX)	140.78	137.88	2%	20,370	9,287	2.2
NeoGenomics (NEO)	15.63	16.18	-3%	2,240	611	3.7
Labcorp (LH)	210.37	227.29	-7%	23,470	12,300	1.9
Guardant Health (GH)	24.00	27.05	-11%	2,990	604	5.0
Psychemedics (PMD)	2.55	2.96	-14%	15	22	0.7
Sonic Healthcare (SHL.AX)*	27.02	32.08	-16%	16,350	8,390	1.9
Opko Health (OPK)	1.26	1.51	-17%	1,240	800	1.6
Biodesix (BDSX)	1.52	1.84	-17%	229	55	4.2
Exagen (XGN)	1.64	1.99	-18%	15	53	0.3
Veracyte (VCYT)	22.50	27.51	-18%	1,440	376	3.8
Fulgent Genetics (FLGT)	22.19	28.91	-23%	-185	288	NA
Exact Sciences (EXAS)	55.59	73.98	-25%	11,800	2,535	4.7
Aspira Women's Hlth (AWH)	2.89	4.08	-29%	37	9	4.0
23andMe (ME)	0.53	0.91	-42%	77	248	0.3
DermTech Inc. (DMTK)	0.63	1.75	-64%	20	15	1.3
Invitae (NVTAQ)	0.01	0.63	-98%	1,250	482	2.6
Biocept (BIOCQ)	0.00	0.04	-100%	5	1	0.2
Totals & Averages			**18%**	**$97,969**	**$38,874**	**2.5**

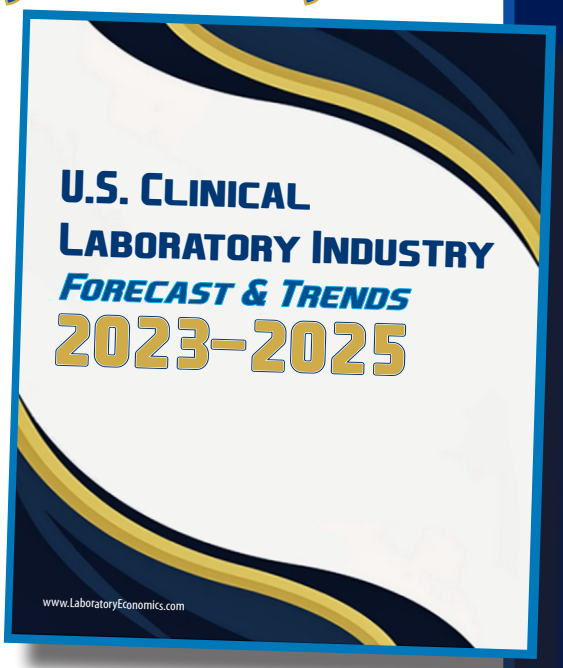
*Sonic Healthcare's figures are in Australian dollars

Source: *Laboratory Economics* from SeekingAlpha.com

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

New from Laboratory Economics

The U.S. Clinical Laboratory Industry
Forecast & Trends 2023-2025



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Our Research Methodology

The U.S. Clinical Laboratory Industry: Forecast & Trends 2023-2025 includes data gathered the old-fashioned way—through primary research. The estimates and market analysis in this report have been built from the ground up, not by regurgitating stale numbers from old reports. Proprietary surveys and extensive interviews with commercial lab executives, hospital lab directors, and respected consultants form the basis of this report. And no stone has been left unturned in our examination of the CLIA database, Medicare test volume and expenditure data, hospital cost reports, Securities & Exchange Commission filings and company annual reports.

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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