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LABORATORY ECONOMICS

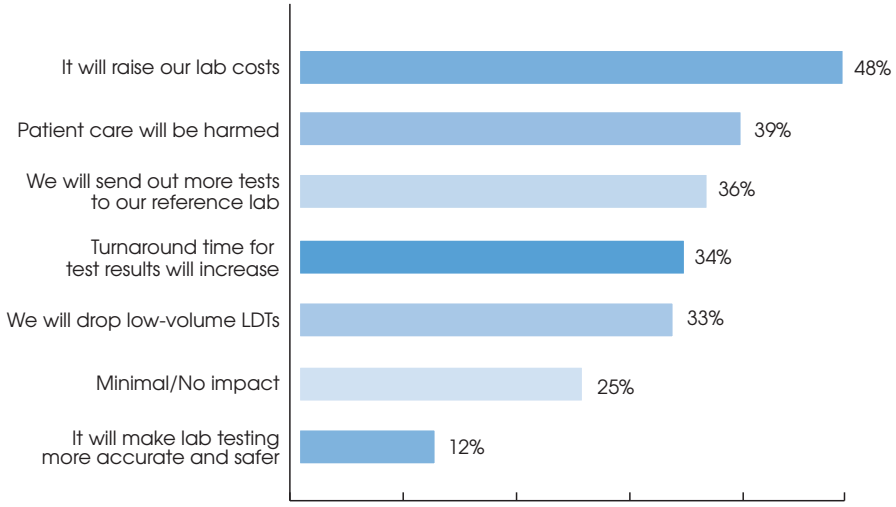
*Competitive Market Analysis For Laboratory Management Decision Makers*

# LDT Regulation Will Raise Costs and Harm Patients

An exclusive *LE* survey has found that 48% of lab directors and executives believe that FDA regulation of LDTs will raise their lab's costs. And 39% said "patient care will be harmed." Only 12% of survey respondents believe FDA regulation will "make lab testing more accurate and safer."

*More survey details on page 3.*

**How will FDA regulation of LDTs affect your laboratory?***




*Survey respondents could pick more than one answer.

Source: *Laboratory Economics Survey* (February 2024; n=126)

# Who Supports FDA Regulation of LDTs?

A total of 6,707 public comments were submitted in response to the FDA's proposed rule to regulate laboratory-developed tests (LDTs). As expected, laboratories, hospitals, academic medical centers and physician groups, including the American Medical Association, are opposed to the agency's plans. Those supporting LDT regulation include America's Health Insurance Plans (AHIP-Washington, DC)—the trade group that represents more than 100 health plans, including Aetna, Cigna, Elevance, Humana, etc.

*Continued on page 2.*

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**WHO SUPPORTS FDA REGULATION OF LDTS?** (*cont'd from page 1*)

"Given the proliferation of laboratory-developed tests and concerns about the reliability of certain LDTs, AHIP supports the FDA's proposal to phase out enforcement discretion for LDTs," according to AHIP.

The **Blue Cross Blue Shield Association** (Chicago, IL), which represents 34 BCBS insurers, also filed comments supporting FDA regulation of LDTs. "Insufficient oversight restricts the ability of health plans to encourage use of the most effective tests by patients and providers, which can also drive higher costs as patients may initiate unnecessary treatment, or delay or forego proper treatment, based on inaccurate test results," according to BCBSA.

However, two large health insurers, **Kaiser Permanente** and **Geisinger Health**, came out against the proposed rule. Unlike most other health insurers, Kaiser and Geisinger are integrated managed care companies that own hospitals, employ physicians and operate labs. "The proposed rule, as written, will severely disrupt our laboratory operations, requiring us to outsource testing to more expensive laboratories," commented Kaiser. And Geisinger said that the proposed rule would affect 136 LDTs that it offers (plus hundreds of IHC antibody stains) as it does not have the resources required to submit these tests for regulatory review.

Not surprisingly, **AdvaMedDx** (Washington, DC), which represents IVD manufacturers (Abbott, Beckman Coulter, Roche Diagnostics, Siemens Healthineers, etc.) is in favor of LDT regulation. AdvaMedDx said that "the proposed rule will not significantly impede the ability of LDTs to reach the market."

Several patient and consumer advocacy groups also support regulation. For example, the **U.S. Public Interest Research Group** (Denver, CO), which was founded by Ralph Nader in 1984, strongly supports LDT regulation and wants the FDA to accelerate its timetable.

The **Association for Clinical Oncology** (ASCO-Alexandria, VA), which represents 50,000 oncology professionals, has long advocated for FDA oversight of LDTs. ASCO noted that the FDA has approved over 180 agents that require assessment of a tumor biomarker for use against more than 300 types of cancer. Many of these cancer drugs have FDA-cleared companion diagnostic (CDx) tests to select patients. LDTs lack the same level of validation as the CDx for many reasons (including, but not limited to, absence of information on the CDx's minimum performance standards), according to ASCO.

The **American Cancer Society's Cancer Action Network** also commented in favor of FDA regulation of LDTs.

| Favor FDA LDT Regulation | Oppose FDA LDT Regulation |
|---|---|
| Abbott | American Medical Association (AMA) |
| AdvaMedDx | American Clinical Laboratory Assn. (ACLA) |
| American Cancer Society's Cancer Action Network | American Hospital Association |
| America's Health Insurance Plans (AHIP) | American Red Cross |
| Assn. for Clinical Oncology (ASCO) | American Society for Clinical Pathology (ASCP) |
| Blue Cross Blue Shield Association | Association for Molecular Pathology |
| Center for Science in the Public Interest | Association of American Medical Colleges |
| Diagnostic Rules for the Future | Children's Hospital Association |
| Foundation Medicine | College of American Pathologists (CAP) |
| Friends of Cancer Research | Geisinger Health |
| NYS Department of Health | Kaiser Permanente |
| U.S. Public Interest Research Group | Senator Rand Paul, MD (R-KY) |

Source: *Laboratory Economics* from public comments (https://www.regulations.gov/docket/FDA-2023-N-2177)

**LDT REGULATION WILL RAISE COSTS AND HARM PATIENTS** (*cont'd from page 1*)
Low test volumes and budget constraints have always been the biggest barriers that labs face when determining if they can add an esoteric test to their in-house test menu. However, the FDA's proposed rule to regulate LDTs—the final rule is due in April—is already impacting lab decision making. Forty-three percent of survey respondents said forthcoming FDA regulation is among the biggest barriers they face in expanding their esoteric testing menu.

*"We would just not be able to launch any LDTs due to cost. There would be no purpose to have a cutting-edge lab that is supposed to integrate new scientific findings into diagnosis. The lab would close,"* according to a pathologist at an academic medical center in Illinois.

*"The cost will increase tremendously, and availability of testing will diminish. The impact is higher cost, lower quality, so a tremendously negative impact on value,"* said a pathologist at an academic medical center in Rhode Island.

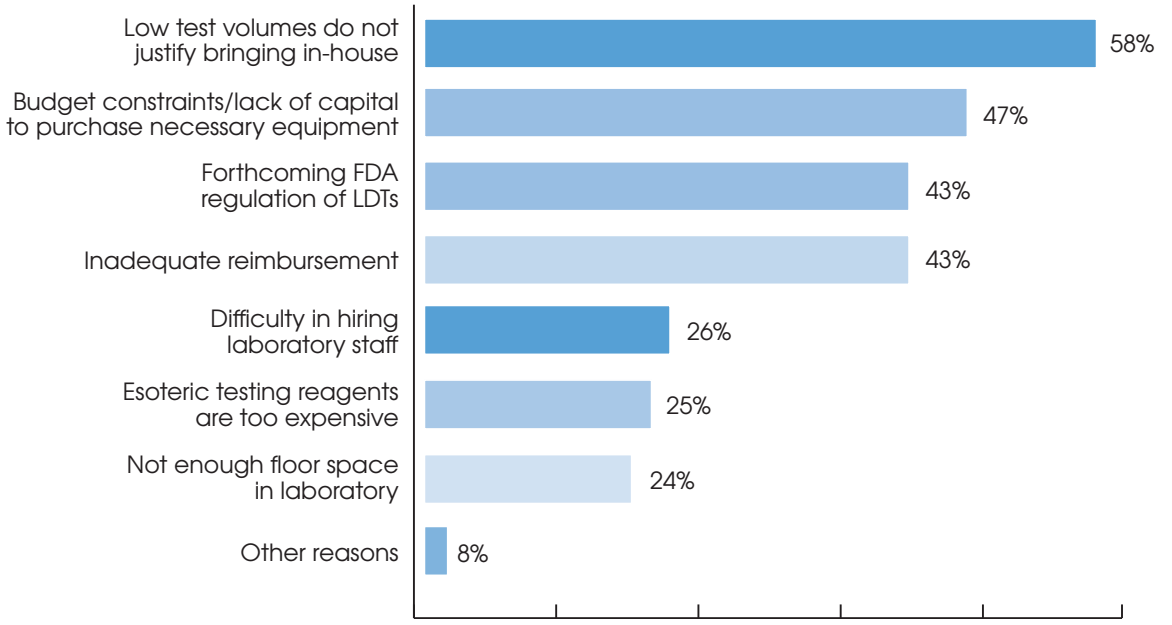
*"FDA regulation will completely disrupt IHC staining and most full-service anatomic pathology labs,"* noted a lab executive from Washington.

However, there was a minority of survey participants in favor of FDA regulation.

*"Regulation of LDTs is long overdue. There is a nexus between the worst behaviors in clinical laboratories and LDTs,"* said a pathologist from New York City.

*"The FDA should regulate LDT testing ASAP. The current 'self-certification' process has minimal oversight and goes on faith that there aren't bad actors. There are a number of pop-up CLIA labs offering bogus molecular assays that should be regulated,"* said a hospital lab director from California.

**What is the biggest barrier your laboratory faces in expanding its esoteric testing menu?***




*Survey respondents could pick more than one answer

**Survey Demographics:** The survey was e-mailed to approximately 8,000 lab directors, managers and pathologists in early February 2024. A total of 126 surveys were judged usable, yielding a response rate of 1.6%. Among the respondents, 60% were from hospital/health system labs; 25% from independent labs; 4% from academic medical centers; 2% from pathology groups; 2% from physician-office-based labs; and 7% from "other" labs.

## Spotlight Interview with Goldbug Strategies' Sheila Walcoff

The FDA's final rule for regulating laboratory-developed tests may come as soon as April. This would give labs only about 3.5 years to develop FDA-compliant quality management systems (QMS's) and begin submitting pre-market applications for their high-risk LDTs. "That may seem like a long time, but it's actually a tight schedule for labs starting at ground zero," according to Sheila Walcoff, Esq., Founder and CEO of Goldbug Strategies (Gaithersburg, MD). Goldbug is a consulting firm that specializes in helping labs and IVD firms navigate FDA regulations.

*Sheila Walcoff, Esq.*

**Is FDA regulation of LDTs a foregone conclusion?**
Yes. Every week I see another sign that LDT regulations will be finalized. There is almost no chance for a legislative solution, such as the VALID Act, given it's an election year and there are other more urgent priorities (Ukraine, the Middle East, the border, etc.). Furthermore, the FDA is actively hiring application reviewers from around the country, including remote workers, in anticipation of an onslaught of LDT applications. FDA also significantly expanded its contract with NDA Partners (Washington, DC) for the purpose of doing LDT reviews.

**Will the final rule grandfather existing LDTs or exempt academic medical centers?**
The short answer is "No."

In its proposed rule, FDA said it will continue to use enforcement discretion only for certain LDTs, such as those used for blood or tissue screening, those used in emergencies, direct-to-consumer tests, and those used for forensics. I expect the final rule may make exceptions for rare disease testing, such as tests for Usher Syndrome and Marfan Syndrome, but will not include a broad grandfathering of all LDTs. Nevertheless, labs can continue to offer existing LDTs and even commercialize new LDTs over the 4-year transition period, so long as they comply with the incremental FDA requirements along the way.

As for academic medical centers (AMCs) and hospitals, FDA Commissioner Robert Califf, MD, appears unpersuaded that such labs should get special treatment as compared with commercial labs. Commissioner Califf has repeatedly indicated that all patients deserve "safe and effective" clinical testing.

**How will modifications to FDA-cleared tests be treated?**
The proposed rule states that modifications made to existing FDA-cleared tests are considered LDTs and will need to go through the FDA review process. I don't expect this to change in the final rule. LDTs that are modified from FDA-cleared tests are likely to be the same risk class as the FDA cleared test unless the modification changes the intended use. If that is the case, the risk class could change (higher or lower).

**What should labs that offer LDTs be doing right now to prepare for regulation?**
Labs need to do a quality management assessment to determine the gaps between FDA standards and the quality procedures they already have in place under CLIA and CAP. FDA just published final regulations changing the quality systems requirements, which will apply both to the lab facility and each LDT.

Many labs will be able to leverage some of what they have and build out standard operating procedures (SOPs) incrementally to support FDA compliance. The focus should be on developing SOP controls that are tailored to the lab and each test. Robust documentation is the best way to keep the FDA "Remote Regulatory Assessment" and onsite inspection nightmares away. Moreover, such SOPs will be needed to justify laboratory Predetermined Change Control Plans (PCCPs).

Labs should also begin to categorize their LDTs by FDA's standards for high-risk and moderate risk. FDA just announced that it intends to "down-classify" most high-risk tests, so labs need to develop a strong FDA focused risk assessment to justify how they have categorized each LDT to avoid unnecessary costs. This needs to be completed before Spring 2026 to meet the anticipated FDA's Stage 2 "registration and listing" deadline.

Finally, labs should be prepared to perform additional validation studies. The FDA will require more validation data (analytical & clinical) for each LDT submitted. Assuming that the FDA publishes its final rule in April or May without changing the timelines, PMA submissions for high-risk LDTs will be due by the fourth quarter of 2027 and moderate-risk LDT submissions will be due by the second quarter of 2028.

**What is the estimated cost for labs to comply with FDA regulation of LDTs?**
The cost to develop FDA-compliant quality management systems, develop more validation data for each LDT, and pay FDA application fees could easily range between $1-2 million for each moderate-risk test and well over $3 million per high-risk test. Labs with novel tests should expect higher compliance costs, even for moderate-risk tests.

**Can you describe the new Predetermined Change Control Plans (PCCPs)?**
PCCPs are detailed plans that labs can submit to FDA with each LDT that describe how the lab would make "post-market" modifications after the initial FDA review. PCCPs drive significant cost savings for labs in an FDA-regulated environment because they enable LDT modifications that would otherwise require additional FDA submissions. PCCPs must reference specific SOPs from an FDA-compliant quality system, so it makes sense for labs to prioritize those for their highest revenue tests at the outset of the FDA compliance timeline.

**How helpful is ISO certification?**
Labs with ISO 13485 certification will have a head start. The FDA published its Final QMS/ISO 13485 Harmonization Rule on January 31. As a result, the FDA has now adopted ISO 13485 quality management system requirements for medical devices, including LDTs. It's almost as if having ISO certification grandfathers a lab into meeting most of the anticipated QMS requirements for LDTs.

**What if the lab industry files a lawsuit seeking to prevent LDT regulation?**
The American Clinical Lab Association (ACLA), and possibly some of its member labs, could file a lawsuit but the legal bar is high when suing the government. ACLA would first need to prove it would be directly harmed by the regulation in order to stand before the court. Also, ACLA would likely seek a permanent injunction to stop the FDA from implementing LDT regulation until the court makes a decision. This would not be a trivial step. In the meantime, labs have no choice but to plan as if FDA regulation of LDTs is coming.

**FDA's LDT to IVD Compliance Timeline**

| 2Q 2025 | 2Q 2026 | 2Q 2027 | 4Q 2027 | 2Q 2028 |
|---|---|---|---|---|
| MDR system required for adverse event reporting/correction/removal for LDTs | Registration & class-based listing, labeling & investigational use | Full QMSR compliance for lab and each LDT | Premarket application (PMA) submissions required for "high-risk" LDTs | FDA submissions required for "moderate-risk" LDTs |
| ***Risks:*** Remote Regulatory Assessment (aka virtual inspection) | ***Risks:*** Virtual inspection and test removal warning | ***Risks:*** All CLIA labs subject to FDA inspection for lab and LDT deficiencies | ***Risks:*** LDT removal, on-site FDA inspection required as part of submission | ***Risks:***LDT removal; post-clearance FDA inspections |

Source: Goldbug Strategies

# Getting the Best Pricing for Your Lab's Next Reference Testing Contract

Reference (aka send-out) testing expenses average between 8% and 14% of the overall budget at most hospital laboratory departments. It represents the second largest expense item for most hospitals—second only to labor, which comprises 40-55%, according to Walt Valliere, Consulting Director, Laboratory and Blood Consulting, Vizient Inc. (Irving, TX). As a result, reference test contracting has the potential to yield significant cost savings. Over the course of his nearly 30-year career in the lab industry, Valliere has helped negotiate more than 200 reference testing contracts. Below is a summary of Valliere's tips for negotiating your lab's next reference testing contract.

**How many send-out tests should be on an RFP for reference testing?**
All of them, because even small volume tests (<500 per year) can add up in cost if they are highly priced. Ideally, a hospital RFP should include every send-out test, its annual volume, and a benchmark price for each test that bidders should seek to match or beat.

**What are your benchmark prices based on?**
We analyze detailed reference laboratory test prices from recent contracts in advance of issuing a new competitive bid or price negotiation for a hospital client. Benchmarking allows a client to understand the cost-savings opportunity and start negotiations from a position of strength.

**What kind of overall savings should a hospital expect when issuing an RFP for reference testing?**
They should expect savings of between 11% and 19% from the RFP process. If the anticipated savings are less than 8% then it's generally not worth the effort of switching to a new reference lab. In this case, the hospital would probably be better off negotiating better pricing from their current reference lab.

**Can you describe the RFP timeline?**
RFPs should be sent to the "big four" reference testing labs—ARUP, Labcorp, Mayo and Quest—as well as Sonic Healthcare and BioReference Labs. Regional labs such as Sonora Quest and Diagnostic Laboratory of Oklahoma should also be considered.

Initial bids should be received within a 30-day deadline. The best two or three bids should be invited to give a presentation and a "best and final" offer. A final decision should be made within four to six months.

**How do you judge non-price metrics like turnaround time?**
The most important factor is always price followed by breadth of test menu. Minimum service level requirements for turnaround time, getting problems resolved, and lost specimens should be specified in the RFP and final contract.

**What's the biggest mistake hospitals make in the RFP process?**
Limiting the number of tests in the RFP request to the top 25 send-outs rather than all send-outs. And having an RFP committee with too many people can turn a 4-6 month process into 12-month process.

### Recent Reference Testing Contracts Managed by Vizient

| Facility | Annual Reference Lab Spend | Benchmark Target Spend | Reference Lab 1 Bid | Reference Lab 2 Bid | Reference Lab 3 Bid | Reference Lab 4 Bid | Best Bid Savings | Best Bid Percent Reduction |
|---|---|---|---|---|---|---|---|---|
| AMC | $23,431,032 | $17,231,055 | $18,133,598 | $17,615,422 | $17,547,633 | $19,882,901 | $5,883,399 | -25% |
| Comm. Hospital | $1,816,322 | $1,404,372 | $1,719,433 | $1,397,456 | $1,801,221 | $2,011,291 | $418,866 | -23% |
| Comm. Hospital | $2,296,710 | $1,745,482 | $1,803,334 | $1,685,303 | $1,749,129 | $2,407,499 | $611,407 | -27% |
| Regional Hospital | $4,402,359 | $3,700,967 | $4,202,989 | $3,788,439 | $3,895,193 | $4,650,174 | $613,920 | -14% |
| Purchasing Coop. | $6,492,475 | $4,930,503 | $5,426,633 | $5,201,917 | $5,011,933 | $6,339,371 | $1,480,542 | -23% |

Source: Vizient Inc.

# Labcorp Reports Full-Year 2023 Financial Results

Labcorp (Burlington, NC) reported net income of $418 million for the full-year 2023, down 67% from $1.3 billion in 2022. LabCorp's overall revenue increased by 2.5% to $12.2 billion in 2023. Revenue from Labcorp's lab testing business increased by 2.3% to $9.4 billion in full-year 2023, including roughly 2-3% growth from acquisitions. On February 15, Labcorp held a conference call with analysts and investors. Here are some comments on a few key topics from CEO Adam Schechter and CFO Glenn Eisenberg.

### Acquisitions and Hospital Lab Deals

Labcorp spent $672 million of cash on acquisitions in 2023. Its biggest deals included the clinical and outreach lab businesses of Tufts Medicine ($157 million), Enzo Biochem ($113 million) and Providence Oregon ($110 million). Most recently, Labcorp purchased the patient service centers and a stat lab from Providence Medical Groups in California [see *LE*, January 2024].

Hospital outreach lab acquisitions are typically accretive to earnings in the first year, with margins expanding over time during integration, and they return their cost of capital within just a few years, according to Schechter.

Labcorp has raised its longer-term goals for growth from acquisitions to 1.5% to 2.5% per year, up from 1% to 2%.

### Labor Shortages

Eisenberg said that the labor market continues to be tight. Employee turnover is still higher than pre-pandemic, but is improving. Labor market inflation is running at 3% to 4% for Labcorp. That translates into between $100 million and $125 million of added expense per year, according to Eisenberg.

### FDA Regulation of LDTs

Labcorp does not support the FDA's proposed rule, which takes legislation that was created for the device industry and applies it to the diagnostic industry, noted Schechter. "We think legislation that is fit for purpose for the diagnostic industry [i.e, VALID Act] is the right path forward." LDTs represent a little less than 5% of Labcorp's overall volume and a higher percentage of its revenue.

### Estoteric Testing

Labcorp's esoteric testing volume grew slightly faster than routine in 2023. Schechter said that Labcorp is focusing new test development on four therapeutic areas: oncology, women's health, autoimmune disease and neurology.

**Labcorp Financial Summary ($ millions)**

| | 2023 | 2022 | % Chg |
|---|---|---|---|
| Total revenue | $12,161.6 | $11,863.9 | 2.5% |
| LabCorp Diagnostics | 9,415.1 | 9,203.5 | 2.3% |
| Biopharma Lab Services | 2,774.2 | 2,697.3 | 2.9% |
| Operating cash flow | 1,327.7 | 1,955.9 | -32.1% |
| Capital expenditures | 453.6 | 429.3 | 5.7% |
| Free cash flow | 874.1 | 1,526.6 | -42.7% |
| Pretax income | 568.9 | 1,237.4 | -54.0% |
| Net income | 418.0 | 1,279.1 | -67.3% |
| Diluted EPS | $4.77 | $13.97 | -65.9% |
| Est'd number of requisitions | 180.8 | 179.5 | 0.7% |
| Est'd revenue per requisition | $52.09 | $51.27 | 1.6% |

Source: Labcorp and *LE*'s estimates for number of reqs and average revenue per req.

# Expert Tips to Help Your Lab Win Health Plan Contracts


*Adam Swain*

Access to in-network insurance contracts has always been one of the biggest challenges faced by independent labs. For insight into how labs can improve their odds of winning contracts, *Laboratory Economics* spoke with Adam Swain, President of Credentials Administrative Services (CAS-Bristol, NH). Over the past 20 years, CAS has helped labs and other providers secure hundreds of health plan contracts. Here's a summary of his advice:

**Why do health insurers make it so difficult for independent labs to get in-network contracts?**
Their focus is on growing their membership base. In general, they believe that if they've got Quest Diagnostics and Labcorp under contract their lab network is complete. Enrolling additional lab providers is not a priority. The one exception is new health plans, which are more receptive to adding labs to their network.

**What can labs do to increase their chances and speed in getting an in-network contract?**
Step one is identifying the name, phone and email for the ancillary contract manager for each health plan you have targeted. They are the ultimate decision maker. Sending a provider application to a general email or mailing address is more often than not a dead end.

**What about the provider application?**
Obviously, it should be filled out completely. In addition, your lab should include at least two or three testimonials from physicians using your laboratory. These physician letters should emphasize, for example, your lab's quick turnaround time, customer service, unique testing services and easy access to pathologists. The letters should also detail the number of health plan patients treated by the physician and how often they order lab tests. You need to build the case that your lab is unique.

**What else should labs do?**
A lab can raise its chances significantly by talking to the ancillary contract manager directly by phone. You should invite the manager to your lab for an onsite visit and meeting with your CEO and/or pathologists.

**How often should a lab reapply?**
Health plans generally evaluate their provider networks every six months to one year. So we recommend reapplying every six months. It doesn't hurt to keep trying. In some cases, we have reapplied as many as six times over the course of two to three years before winning an in-network contract.

**What kind of success rates should labs expect?**
We secure an average of roughly 50% of the contracts we attempt on behalf of lab clients. CAS earns half of its fee for helping labs submit their applications. We get the other half only after an in-network provider contract is won.

**What is the most common reason that health plans deny an in-network provider contract?**
The most common reason given is that their network is "at capacity" for laboratory services. If the health plan feels that their existing contracted labs meet the needs of their members, they often do not see a reason to add more.

**Is there any opportunity for independent labs to negotiate higher fee schedules?**
Generally not, although smaller labs providing higher service levels deserve higher rates than the big commercial labs. Insurers expect smaller labs to be cost effective or cost neutral as compared with Quest or Labcorp.

**Why not stay out-of-network and get paid more?**
Most physicians abide by their insurance contracts and refer only to in-network labs. Physicians are also sensitive to balance billing to patients.

# Quest Reports Full-Year 2023 Financial Results

Quest Diagnostics reported net income of $854 million for full-year 2023, down from $946 million in 2022. Quest's overall revenue declined by 6.4% to a $9.3 billion, with acquisitions contributing roughly 0.5% to revenue growth. The revenue decline was the result of an 85% drop in Covid testing revenue to $223 million. Quest's average revenue per requisition fell by 5.9% to an estimated $44 per req. A summary of key topics discussed by CEO Jim Davis and CFO Sam Samad on a February 1 conference call follows.

**FDA Regulation of Laboratory-Developed Tests**

LDTs comprise approximately 10% of Quest's test menu and slightly less than 10% of its overall volume. Davis said that the FDA does not have the statutory authority to unilaterally regulate LDTs and believes that legislative change [e.g., the VALID Act] is the appropriate path.

Davis noted that Quest does a lot of work for pharmaceutical clients and international labs—both of which require Quest to be ISO-certified [International Organization for Standardization]. "When you're doing work for the pharmaceutical industry, especially in companion diagnostics, you're essentially operating already under FDA regulations." So LDT regulation would not be a "heavy lift" for Quest. Quest's lab in San Juan Capistrano, CA is ISO 13486 accredited, and its sites in Marlborough, MA and Lewisville, TX, among others, are ISO 15189 accredited.

"If we do get additional regulation, we think this is going to be a challenge for smaller labs, particularly academic medical centers…. We don't want additional regulation, but there are opportunities around getting more reference work from hospitals," noted Samad.

**Direct-to-Consumer Testing**

Davis said that Quest's direct-to-consumer [DTC] testing service, questhealth.com, generated revenues of approximately $45 million in 2023 with favorable returns on ad spending and customer acquisition costs. In addition, Quest performs DTC testing for third parties and recorded more than $30 million through this channel in 2023. New DTC tests that Quest has introduced include a blood test for PFAS (aka forever chemicals—see page 10). Davis said that Quest's DTC business is now operating profitably and does not require incremental investments.

**Employee Wage Inflation**

Quest is instituting 3% wage increases across the board this year, following wage inflation of 4% in 2023. Labor turnover is now in the low 20% versus the mid-teens in pre-pandemic 2019. Davis said that lowering employee turnover offers the greatest upside for cost savings in 2024.

**Quest Diagnostics Financial Summary ($ millions)**

| | 2023 | 2022 | % Chg |
|---|---|---|---|
| Total revenue | $9,252 | $9,883 | -6.4% |
| Base lab testing revenue | 9029 | 8,428 | 7.1% |
| Covid-19 testing revenue | 223 | 1,454 | -84.7% |
| Operating cash flow | 1,272 | 1,718 | -26.0% |
| Capital expenditures | 408 | 404 | 0.9% |
| Free cash flow | 864 | 1,314 | -34.2% |
| Pretax income | 1,130 | 1,235 | -8.5% |
| Net income | 854 | 946 | -9.7% |
| Diluted EPS | $7.49 | $7.97 | -6.0% |
| # Employees | 49,500 | 50,000 | -1.0% |
| Avg. revenue per employee | $186,909 | $197,660 | -5.4% |
| Est'd number of requisitions (millions) | 206.5 | 207.8 | -0.6% |
| Est'd revenue per requisition | $43.67 | $46.25 | -5.9% |

Source: Quest Diagnostics and LE's estimates for number of reqs and average revenue per req.

**Fastest-Growing Tests**

Quest reported double-digit volume growth in 2023 in several segments: advanced cardiometabolic, prenatal and hereditary genetics, and neurology testing.

## Quest Diagnostics to Buy Lenco Diagnostic Laboratories

In January, Quest entered into a definitive agreement to acquire select assets of Lenco Diagnostic Laboratories (Brooklyn, NY). Lenco is an independent lab founded in 2002 by its CEO Tilman Lenny. Lenco operates a CAP-accredited lab in Brooklyn and has 18 patient service centers in New York City. The company has approximately 239 employees and estimated annual revenue of $50 million. Lenco's test volumes are expected to be shifted to Quest's regional lab in Clifton, New Jersey (20 miles west of Brooklyn). Lenco is planning to lay off 185 of its 239 employees effective April 15, according to a WARN report filed with the New York State Department of Labor on January 15.

## Quest Diagnostics Launches $256 Test for Forever Chemicals

Quest Diagnostics is now offering a PFAS ("Forever Chemicals") blood test panel directly to consumers. The test is available for direct purchase on questhealth.com at a price of $256, which includes a $7 payment to PWNHealth to review test orders. Quest's PFAS Test Panel checks for nine of the most common PFAS chemicals that have been linked with certain health risks, including increased cholesterol levels and kidney and testicular cancer. The test is intended for people in high-risk situations (e.g., firefighters, industrial workers, etc.) to get a sense of how badly they've been exposed so they can look into ways to reduce the exposure.

## Invitae Files for Bankruptcy to Deal with $1.5 Billion Debt

Invitae Corp. (San Francisco, CA) filed for Chapter 11 bankruptcy protection in the U.S. Bankruptcy Court for the District of New Jersey on February 13. The company plans to run a five-month bankruptcy sale process to find a buyer and exit from Chapter 11 by late July. U.S. Bankruptcy Judge Michael Kaplan has approved the company's proposed bid procedures and set an April 10 deadline for initial bids. Invitae has already received some initial bids, Invitae attorney Nicole Greenblatt told Judge Kaplan.

Invitae has $1.5 billion in debt on its balance sheet. Its biggest creditor is the Japanese investment holding company SoftBank (Tokyo). Invitae raised $1.2 billion in convertible debt from SoftBank in 2021.

Invitae, which has roughly 1,400 employees, operates CLIA-certified labs in California, North Carolina and New Jersey that specialize in genetic testing. In January, Invitae sold its reproductive health business, which includes carrier screening and non-invasive prenatal screening, to Natera for $52.5 million.

In the 12 months period ended Sept. 30, 2023, Invitae recorded a net loss of $1.4 billion on revenue of $482 million. Invitae has accumulated losses totaling $6.2 billion since its inception in 2013.

Invitae had reached an enterprise value of $9 billion and traded as high as $56 per share back in December 2020. Invitae currently trades below 5 cents and the stock has been delisted from the NYSE.

**Invitae Financial History ($000)**

| | *Latest 12 Months thru 9/30/2023* | *2022* | *2021* | *2020* |
|---|---|---|---|---|
| Revenue | $481,583 | $516,303 | $460,449 | $279,598 |
| EBITDA | -1,278,314 | -2,952,379 | -285,491 | -645,454 |
| Pretax Income | -1,454,026 | -3,151,197 | -415,863 | -714,270 |
| Net Income | -1,440,618 | -3,106,293 | -379,006 | -602,170 |
| Total Debt | 1,510,000 | 1,751,003 | 1,724,096 | 450,137 |
| Cash & Securities | 254,573 | 547,100 | 1,045,371 | 353,980 |

Source: *Laboratory Economics* from Invitae financial reports

# OIG Scrutinizes Purchased Services Arrangements for TC Services

Anatomic pathology (AP) labs should be cautious when considering purchased service agreements with physician-owned labs. This message was delivered by the Office of Inspector General (OIG) through an Advisory Opinion (AO 23-06) issued September 25, 2023.

AO 23-06 contemplated a proposed arrangement under which an independent AP lab would purchase the technical component (TC) from what appeared in the description to be primarily physician-owned labs. The independent AP lab would perform the professional component (PC) and bill commercial insurers as an in-network provider for the global (TC & PC) amount. The independent AP lab would then pay the physician-owned lab a fair market value for performing the TC.

*Elizabeth Sullivan, Esq.*

The OIG' ultimately determined that the purpose of the proposed arrangement was to allow the physician-owned lab to gain access to the independent AP lab's commercial payer contracts. These types of arrangements are often contemplated when physician groups with in-house pathology labs (e.g., gastroenterology and dermatology practices) have commercial payer contracts that exclude technical lab services, or reimburse at low levels, according to Elizabeth Sullivan, Esq., Chair of McDonald Hopkins' national Healthcare Practice Group. Over the years, Sullivan says that commercial payers have made it more and more difficult for physician-office-based labs to bill and get paid for AP technical services.

The OIG concluded that the proposed arrangement was not commercially reasonable and implicated the Anti-Kickback Statute. In explaining its conclusion, the OIG highlighted the following facts:

- The proposed arrangement would allow the independent AP lab to give the physician-owned lab the opportunity to receive payment for TC services they would otherwise not be able to bill due to their out-of-network status.
- In most instances, the billing lab had the ability to perform the TC and PC itself and doing so was generally more efficient and cost-effective than paying a third party to perform the TC.
- Because the physician-owned lab did not have contracts that allowed it to bill commercial insurers for TC services, the lab would be more likely to refer PC services to the independent AP lab.
- Entering into the proposed arrangement would likely result in referrals of federal healthcare program business to the independent AP lab and, conversely, if the parties did not enter into the proposed arrangement, it likely would not receive a significant volume of referrals, including federal healthcare program business, from the physician-owned lab.

Sullivan says that the OIG perceived the arrangement as an attempt by the physician-owned lab to gain "backdoor" access to the independent AP lab's commercial insurance contracts. The OIG found no commercially reasonable business purpose for the billing laboratory to enter into the proposed arrangement and forego "the opportunity to bill and retain payment for both components of the anatomic pathology services, in an arrangement that is both less efficient and more costly —other than the possibility that such payment may induce referrals of patients, including federal healthcare program beneficiaries."

The appropriate course of action would be for the physician-owned lab to either bill commercial insurers directly for the services that it performed and accept reimbursement or refer all of its out-of-network business (TC & PC) to an independent AP lab, according to Sullivan. The independent AP lab would then perform the complete service, bill for the services that it performed, and keep the global payment.

# Lab Stocks Down 10% Year-to-Date In 2024

Twenty-four lab stocks have dropped by an unweighted average of 10% year to date through February 16. In comparison, the S&P 500 Index is up 15% year to date. The top-performing lab stocks thus far in 2024 are GeneDx, up 84%; Myriad Genetics, up 21%; and Aspira Women's Health, up 18%. Labcorp shares are down 5% and Quest Diagnostics is down 10%.

| Company (ticker) | Stock Price 2/16/24 | Stock Price 12/29/23 | 2024 Price Change | Enterprise Value ($ millions) | Revenue for Trailing 12 mos. ($ millions) | Enterprise Value/ Revenue |
|---|---|---|---|---|---|---|
| GeneDx (WGS) | $5.05 | $2.75 | 84% | $90 | $207 | 0.4 |
| Myriad Genetics (MYGN) | 23.25 | 19.14 | 21% | 2,180 | 734 | 3.0 |
| Aspira Women's Hlth (AWH) | 4.83 | 4.08 | 18% | 54 | 9 | 5.8 |
| Castle Biosciences (CSTL) | 25.30 | 21.58 | 17% | 466 | 192 | 2.4 |
| Natera (NTRA) | 70.01 | 62.64 | 12% | 7,920 | 989 | 8.0 |
| ProPhase Labs (PRPH) | 4.98 | 4.52 | 10% | 104 | 63 | 1.7 |
| Exagen (XGN) | 2.14 | 1.99 | 8% | 33 | 52 | 0.6 |
| Psychemedics (PMD) | 2.97 | 2.96 | 0% | 19 | 23 | 0.8 |
| Sonic Healthcare (SHL.AX)* | 31.94 | 32.08 | 0% | 17,550 | 8,170 | 2.1 |
| Labcorp (LH) | 216.64 | 227.29 | -5% | 24,070 | 12,162 | 2.0 |
| Interpace Biosciences (IDXG) | 1.05 | 1.08 | -3% | 60 | 38 | 1.6 |
| Quest Diagnostics (DGX) | 124.00 | 137.88 | -10% | 18,740 | 9,252 | 2.0 |
| Veracyte (VCYT) | 24.74 | 27.51 | -10% | 1,620 | 343 | 4.7 |
| NeoGenomics (NEO) | 14.36 | 16.18 | -11% | 2,030 | 575 | 3.5 |
| Fulgent Genetics (FLGT) | 25.40 | 28.91 | -12% | -76 | 286 | -0.3 |
| 23andMe (ME) | 0.78 | 0.91 | -14% | 212 | 248 | 0.9 |
| Guardant Health (GH) | 22.42 | 27.05 | -17% | 2,920 | 536 | 5.4 |
| Exact Sciences (EXAS) | 60.97 | 73.98 | -18% | 12,870 | 2,406 | 5.3 |
| Biodesix (BDSX) | 1.48 | 1.84 | -20% | 166 | 44 | 3.8 |
| DermTech Inc. (DMTK) | 1.33 | 1.75 | -24% | 33 | 14 | 2.3 |
| CareDx (CDNA) | 8.13 | 12.00 | -32% | 206 | 297 | 0.7 |
| Opko Health (OPK) | 1.01 | 1.51 | -33% | 873 | 867 | 1.0 |
| Invitae (NVTAQ) | 0.02 | 0.63 | -97% | 1,260 | 482 | 2.6 |
| Biocept (BIOCQ) | 0.00 | 0.04 | -100% | 5.0 | 1.4 | 3.5 |
| Totals & Averages | | | -10% | $93,404 | $37,989 | 2.5 |

*Sonic Healthcare's figures are in Australian dollars

Source: *Laboratory Economics* from SeekingAlpha.com



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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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