LABORATORY *e* ECONOMiCS

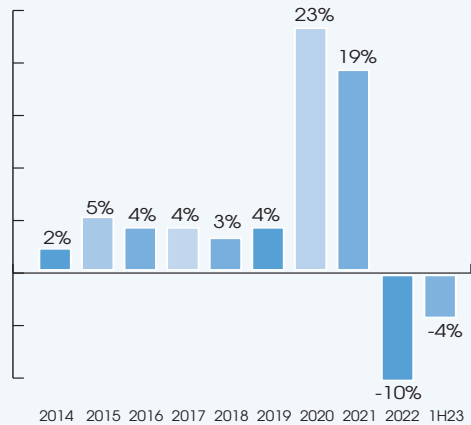*Competitive Market Analysis For Laboratory Management Decision Makers*

Techcyte AI Targets Clinical Lab Testing

Techcyte (Orem, UT) is developing AI algorithms that could help understaffed microbiology, hematology and cytology lab departments speed up labor-intensive microscopic analysis. The company's AI products hold the promise of reducing medical technologist's average time on the microscope from 3 to 5 minutes per slide to 15 to 30 seconds. *Full details on pages 4-5.*

The Covid Testing Boom & Bust Is Over

Demand for Covid-19 PCR testing bottomed out in the first half of this year at the nation's publicly traded lab companies. On a combined basis, 24 publicly traded labs reported a revenue drop of 4.1% to reach $13.9 billion during the first six months of 2023 (after adjusting for acquisitions), according to financial reports collected by Laboratory Economics. This followed the record-breaking growth these labs reported in 2020 and 2021. However, even after the drop off, annualized revenue at publicly traded labs is still more than 30% higher than pre-pandemic levels in 2019. *Continued on page 10-11.*
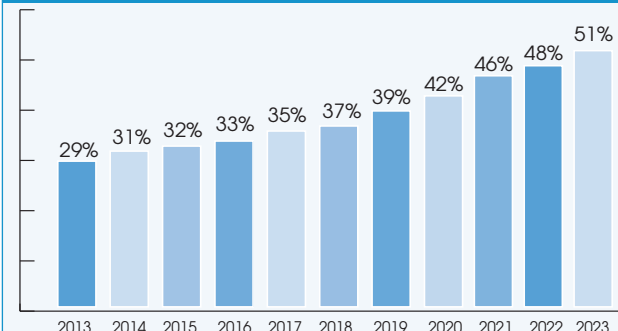
Revenue Growth at Publicly Traded Labs

2014: 2% / 2015: 5% / 2016: 4% / 2017: 4% / 2018: 3% / 2019: 4% / 2020: 23% / 2021: 19% / 2022: -10% / 1H23: -4%

Source: *Laboratory Economics* from company reports

Medicare Advantage Plans Put Labs at Disadvantage

In 2023, 30.8 million people are enrolled in a Medicare Advantage plan, accounting for more than half (51%) of the eligible Medicare population. The ongoing membership shift from traditional Medicare to Medicare Advantage plans has important implications for all providers, especially independent pathology groups and clinical labs. For a full analysis, *see page 2.*

Percentage of Recipients Enrolled in Medicare Advantage Plans

2013: 29% / 2014: 31% / 2015: 32% / 2016: 33% / 2017: 35% / 2018: 37% / 2019: 39% / 2020: 42% / 2021: 46% / 2022: 48% / 2023: 51%

Source: Kaiser Family Foundation and CMS

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MEDICARE ADVANTAGE PLANS PUT LABS AT DISADVANTAGE (*cont'd from page 1*)
PAMA surveys and resulting rate cuts to the Medicare Clinical Lab Fee Schedule (CLFS) get most of the attention from the clinical lab industry. But the accelerating shift in enrollment from traditional Medicare to Medicare Advantage plans may be having a bigger impact on clinical labs and pathologists.

Medicare Advantage Plans, also called "Part C" or "MA" plans, were introduced under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, which was enacted in December 2003.

MA Plans are offered by private insurance companies. The Medicare program pays these companies a fixed payment for each Medicare beneficiary they cover. MA plans earn profits by managing health expenses below the fixed payments they receive.

Medicare Advantage Enrollment (millions)
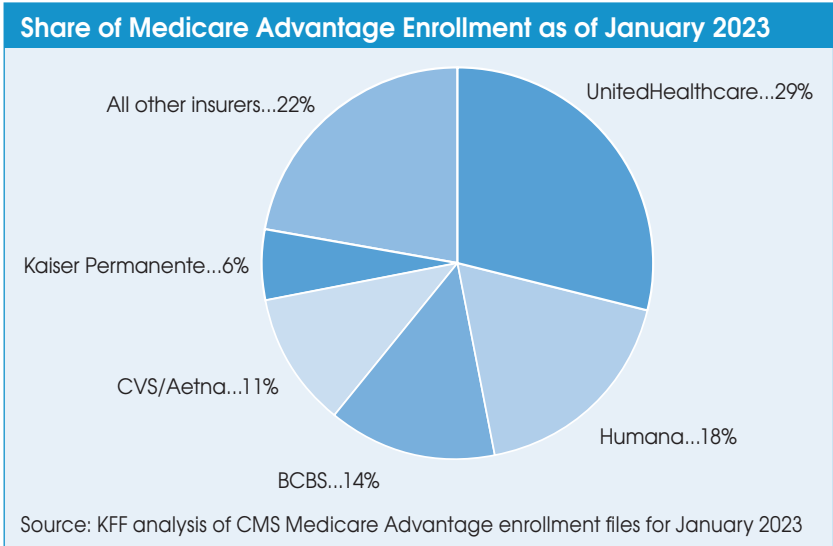

Source: KFF and CMS
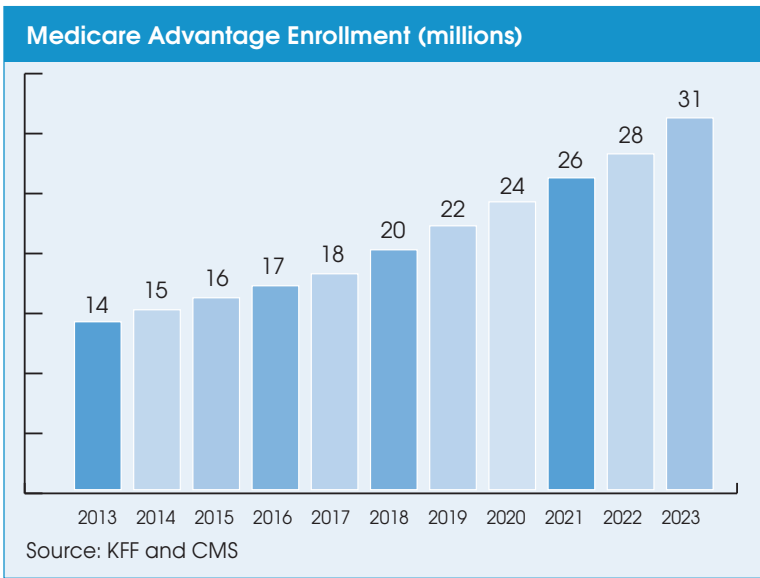
During the ten-year period from 2013 to 2023, enrollment in MA plans grew from 14 million to 30.8 million, or an average of 9.9% per year. Over the same time frame, enrollment in traditional Medicare fell from 27.1 million to 25.8 million.

MA plan enrollment has been growing because most do not charge enrollees more than the $165 per month cost of traditional Medicare and yet they provide extra benefits, including drug, vision, dental and hearing benefits.

In addition, MA plans cap out-of-pocket expenses so there is less of a need for Medigap supplemental policies. The average Medicare beneficiary in 2023 has access to 43 MA plans, the largest number of options ever, according to data from Kaiser Family Foundation (KFF) and CMS.

UnitedHealthcare has the biggest and fastest growing MA plan membership. UHC added one million MA members in the past year to reach a total of 8.9 million as of January 2023. Humana added 513,000 MA members for a total of 5.5 million. Together, UHC and Humana account for nearly half (47%) of all MA enrollees nationwide.

MA plans earn profits by

Share of Medicare Advantage Enrollment as of January 2023

Source: KFF analysis of CMS Medicare Advantage enrollment files for January 2023

managing health expenses below the fixed per-member payments they receive from the Medicare program. For this reason, MA plans are highly incentivized to lower costs.

Tighter Lab Networks
Under traditional Medicare, any lab can provide testing services for any beneficiary. However, private health insurers offering MA plans typically contract with a limited network of lower-cost labs. And some MA plans have exclusive contracts with either Quest Diagnostics (eg., BCBC Florida Blue – BlueMedicare HMO and PPO) or Labcorp (eg., Wellcare Medicare Advantage in Florida). As a result, independent labs, hospital outreach labs and local pathology groups can be shut out of serving these members.

Prior Authorization Requirements
Nearly all Medicare Advantage enrollees (99%) are in plans that require prior authorization for some services, according to KFF. Prior authorization requirements are generally not used in traditional Medicare.

Lower Reimbursement Rates
MA plans generally pay independent labs at rates below the Medicare CLFS. MA plans managed by Aetna, Cigna and UHC are the ones that often pay less, according to James John, CEO of the billing firm Commit Services (New York City). In addition, a study published in *JAMA Internal Medicine* found that MA plans pay independent labs an average of only 76% of the Medicare CLFS rate for a complete blood cell count (CPT 85025)—see *JAMA Intern Med*; Sept. 2017, pp. 1287-1295.

Update on SALSA Bills to Stop Medicare CLFS Rate Cuts

After failing to pass into law last year, the Saving Access to Laboratory Services Act (SALSA) was reintroduced earlier this year in both houses of Congress. SALSA would set Medicare CLFS rates based on a statistical sample of private payer rates from independent labs, hospitals and physician office labs.

On March 28, 2023, SALSA (Sen. 1000) was reintroduced in the Senate by Sherrod Brown (D-OH) and Thomas Tillis (R-NC). It has gained support from two cosponsors Debbie Stabenow (D-MI) and Ted Budd (R-NC).

On March 29, 2023, SALSA (HR. 2377) was reintroduced in the House by Richard Hudson (R-NC). It has gained support from 36 cosponsors (19 Democrats, 17 Republicans).

Without legislative action, Medicare CLFS rates for almost 800 tests will receive rate cuts of up to 15% effective January 1, 2024. In addition, labs would need to report their private-payer payment data from 2019 to CMS between January 1 and March 30, 2024. CMS would use this information to calculate the CLFS for 2025-2027.

Potential for Another Rate Freeze
Getting SALSA passed into law may prove difficult because preliminary estimates from the Congressional Budget Office pegged its cost at $6 billion over 10 years (see *LE*, December 2022).

Laboratory Economics believes the most likely outcome could be another one-year freeze in Medicare CLFS rates for 2024 as well as a delay in lab payment data reporting. That's because a one-year delay would actually save CMS an estimated ~$730 million over 10 years and not require offsetting "pay fors." The Medicare CLFS has already been frozen for three consecutive years (2021-2023) for this same reason.

TECHCYTE AI TARGETS CLINICAL LAB TESTING (*cont'd from page 1*)

Ben Cahoon

Techcyte hired computer scientist and entrepreneur Ben Cahoon as CFO/COO in 2016, and he became Chief Executive in May 2020. Our Q&A with Cahoon is summarized below:

Who founded Techcyte?
Our Chairman Ralph Yarro founded Techcyte in 2013 after purchasing the research of Mohamed Salama, MD, from the University of Utah. Yarro is also Managing Director of Atua Ventures, a Provo, Utah-based venture capital firm.

Yarro formed Techcyte and identified the potential for its cellular digital pathology technology to address not only human medical testing, but veterinary and environmental testing as well.

How much money has Techcyte raised to date?
A total of $38 million. This includes our latest Series E round of $21 million in August. Investors include ARUP Laboratories, Mayo Clinic Laboratories and Zoetis Inc. (Parsippany-Troy Hills, NJ). Techcyte employees also own a substantial stake.

Can you describe your technology?
We've developed a cloud-based AI platform that uses AI algorithms to analyze digitized slide images of liquid and cell-based samples.

We chose to focus on the liquid market, including fecal, Pap smears, blood and urine samples, because it's less crowded than the tissue-based market. Microbiology is also one of the only remaining segments in clinical diagnostics that has not yet been automated.

In brief, the process involves lab clients sending their digitized slide images to our cloud-based system. Our AI programs analyze the images—finding, classifying and counting cells—and makes a proposed test result. The proposed result is reviewed and signed off on by the lab client's medical technologist or pathologist.

How does the Techcyte AI actually work?
Techcyte AI analyzes each digitized slide image at a pixel level using an object detection network. The AI breaks down each image into thousands of features based on pixel colors, angles, shapes and textures, etc. These features are then put through a convolutional neural network that statistically determines whether a particular object is present on the slide. Medical technologists and pathologists view the predicted results as an assistive tool to make a final diagnosis.

You first introduced your system to the veterinary market.
That's right. Our AI platform has been used by Zoetis to analyze digitized slide images of fecal, urine and blood samples from dogs, cats and horses since September 2020. Zoetis markets this service under the brand name Vetscan Imagyst.

Zoetis is the world's largest maker of medicine and vaccinations for pets and livestock. It also has a diagnostic products and lab services division focused on the veterinary market.

The veterinary lab market is much bigger than most people realize. For example, veterinary fecal tests total 100 million tests per year worldwide.

Our most popular AI program analyzes fecal slide images for ova (eggs) and parasites in a matter of 15-30 seconds. This compares with a 3–4-minute turnaround time using a traditional microscope and human analyst.

We're on track to complete one million AI-assisted tests for Zoetis this year, bringing Techcyte to a cumulative total of three million tests over the past three years.

Can you describe the workflow process in the veterinary lab market?
Zoetis sells the software solution, scanner and consumables to veterinary clinics, where the slides are made, scanned in and sent to Techcyte's AI platform. The results are delivered back to the veterinary clinic and input in each animal's medical record.

Where is Techcyte in terms of the human diagnostics market?
Four years ago, ARUP Labs and Techcyte collaborated to produce the world's first AI-assisted ova and parasite detection tool for use as a laboratory-developed test on digitized fecal slide images in ARUP's parasitology lab. The technology enables laboratorians to quickly screen out negative results so they can spend more time analyzing slides that show positive results.

How accurate is AI-assisted testing for ova and parasite detection?
A clinical validation study led by ARUP microbiologist Blaine Mathison showed positive agreement was 98.88%, and negative agreement was 98.11%, compared with traditional microscopy. The Techcyte AI algorithm was 5-fold more sensitive than manual examinations by multiple parasitologists. Study results were published in the *Journal of Clinical Microbiology* (June 2020).

Techcyte recently signed a partnership with Mayo Clinic Laboratories.
Yes. Earlier this year we announced a strategic collaboration with Mayo Clinic to create new AI algorithms on our Techcyte Clinical Pathology AI Platform.

Some of the potential testing segments that this partnership might focus on include gram stains for bacteria, Pap testing, hematology and bladder cancer surveillance on cytology slides.

Techcyte has exclusive commercialization rights to AI algorithms developed from this partnership.

How much will it cost for labs to use Techcyte's AI programs?
Techcyte workflow and AI is priced per slide. The pricing for most indications starts at about $5 per slide, but then goes down to about $2 at the highest volume discounts.

Does Techcyte have a preferred slide scanning system?
No, our AI algorithms can be applied to images digitized by almost any scanning system, including Grundium, Hamamatsu, Leica, 3D-Histech, etc.

Will the lack of slide-scanner placements at labs inhibit the growth of Techcyte?
Up until now, there has been no reason for clinical labs to digitize slides. However, the increased efficiency provided by AI creates a return-on-investment for labs that adopt digital pathology. AI algorithms can analyze a slide image in a matter of a few seconds, freeing up time for MTs to focus their attention on confirming and characterizing positive cases. Given the long-standing MT shortage, especially in microbiology departments, the case for investing in digital pathology with AI is compelling.

Any plans to seek FDA clearance for Techcyte's AI programs?
Yes, we have submitted for a 510k for our WBC/RBC automated differential, have submitted multiple q-subs for pre-submission feedback, and will be seeking clearance for additional indications in the near future.

Can you describe Techcyte's AI programs for the environmental testing market?
Techcyte already has an air quality test that identifies 160 different kinds of mold, particulate and pollen. We sell to environmental labs throughout the world and also operate a lab here in Utah that runs home inspections samples. In the future we'll have tests for algae, food and soil testing.

Vitestro Launches Study for Robotic Blood Drawing Machine

Netherlands-based Vitestro Holdings has enrolled the first 350 patients into its ADOPT (Autonomous Optimization and Performance Tests for Blood Testing) Trial at Result Laboratorium in the Albert Schweitzer Hospital (Dordrecht, The Netherlands). Other study sites include St. Antonius Hospital, OLVG Lab and Amsterdam UMC. Ultimately, Vitestro anticipates the study will have a sample size of over 10,000 patients.

The company's device utilizes ultrasound-guided, AI-based 3D reconstruction with robotic needle insertion to collect a user's blood. The device, which is a little bigger than a kitchen refrigerator, is intuitive to use and allows patients to manage the full blood collection procedure on their own, according to Christine Strik, Marketing Manager for Vitestro.

The Vitestro Blood Drawing Machine

One healthcare professional is able to supervise several Vitestro devices, managing multiple patients simultaneously. Strik says that the increased efficiency will enable hospitals and laboratories to address workforce shortages and free up staff to deploy them where they are needed most.

The national average pay for phlebotomists in the United States is about $19 per hour, or $39,000 per year, according to the U.S. Bureau of Labor Statistics.

Vitestro anticipates it will get a CE mark and introduce the product into the European market in 2024. The company also plans to bring this product to the U.S. market, although no timetable is set.

Vitestro raised $12.9 million from a Series A financing in March. The funding was led by Sonder Capital (San Carlos, CA). Other investors include Netherlands-based Addington Investment Group and European Innovation Council (Brussels, Belgium). Vitestro plans to use the proceeds to expedite product development, prepare EU market authorization and initiate production.

Ibex Raises $55 Million

Ibex Medical Analytics (Tel Aviv, Israel) has announced the close of a Series C financing round that raised $55 million. Ibex has now raised a total of more than $100 million since being formed in 2016.

The latest funding was led by 83North (London, England), which was joined by Sienna Venture Capital, Octopus Ventures, aMoon, Planven Entrepreneur Ventures and Dell Technologies Capital.

Ibex's Galen software products use AI to assist pathologists with analysis of digitized slide images. Its clients include CorePlus (Puerto Rico), Alverno Laboratories (Hammond, IN) and University of Pittsburgh Medical Center (UPMC).

PathGroup Moving Toward 100% Digital Pathology

PathGroup (Nashville, TN) is the largest privately held pathology lab company in the United States. Its 225 pathologists serve more than 15,000 referring physicians and over 200 hospitals. PathGroup, which processes about 4 million slides per year, went live with digital pathology in March 2020. Here's a summary of our Q&A with Derek Welch, MD, Chief Medical Officer and Executive Vice-President at PathGroup:

Derek Welch, MD

What were some of the factors that convinced PathGroup to get into digital pathology?
Our decision was driven by three primary parameters. First, we anticipated an improvement in professional service quality. Secondly, there was an expectation that we would improve pathologist productivity and efficiency. Lastly, we were waiting for FDA endorsement of a complete platform, so FDA-approval of the Philips solution for primary diagnostic use in 2017 allowed for proceeding with an investment.

In addition, AI algorithms may eventually augment quality and efficiency. But you can't use AI unless you've got digitized slide images.

How many scanners does PathGroup have installed?
We've got a total of 28 scanners at six locations. The majority are installed at our main anatomic pathology lab in Nashville, although we also have scanners at select hospitals and dermatopathology labs. We're using Philips UFS scanners and moving new installations to their SG300 model, which produces higher-quality images.

Philips high-definition monitors are used by our pathologists to view digitized slide images.

We're also using Proscia's Concentriq Dx viewer software, which allows pathologists to quickly manipulate digitized slide images and move from slide to slide, with scanner agnostic capability.

Was there any reluctance from your pathologists?
The overwhelming majority of our initial user pathologists were on board with digital pathology from the beginning. There was a minority, less than 10%, who were initially skeptical about the ability to fluidly move from slide to slide using digitized images versus their microscope.

Can you describe PathGroup's progress in transitioning to digital pathology?
About 30% of our pathologists made a 100% transition to reading digitized images in March of 2020. On a Friday in early March, they used their microscope and on Monday they were signing out cases from their computer monitors. The transition covered all cases except for cytology and bone marrow biopsies.

The learning curve was very short. Our pathologists became comfortable with digital pathology in a matter of a few days.

Currently, about 35% of our pathologists have switched to digital pathology. Our plan is to reach 100% within the next few years.

Are your pathologists reading many digitized slides from home?
We have cohorts of pathologists that are reading entirely from home, and others that hybridize their office and hospital read time with additional home reading capabilities.

Has PathGroup realized efficiencies through digital pathology?
We have found that pathologists are faster using their computer screen and mouse versus the

microscope. They are moving more quickly from slide to slide and between separate cases. Less time is spent with activities such as changing objective magnification levels, organizing paperwork and slides, and confirming slide identity.

Digitization has also sped up turnaround times. We scan slide images throughout the day and these images are immediately available for pathologist interpretation.

Finally, digital pathology allows our pathologists to share difficult cases with their colleagues throughout the country almost in real time. Second opinions are received in five minutes as compared to 24 hours or more when shipping glass slides.

What advice would you give other labs considering digital pathology?
You need to identify a group of employees who will earnestly champion digital pathology, including pathologists, histotechs and IT staff. These champions can help plan and manage the transition.

Don't underestimate the importance of image management in terms of where to store images, how to distribute and assign cases, and how long to store. We are storing our digital slide images for three months. And we continue to store our physical slides forever.

Finally, labs need to realize that although going digital is not cheap, there can be a return on investment (ROI). The ROI is achieved through increased pathologist productivity. But you've got to be willing to adjust your pathologist staffing model and caseloads.

**Where is PathGroup in terms of adding AI tools for pathologists?**
AI for pathology is still a naïve market. We're vetting different vendors and their AI algorithms. We're looking for best-in-class algorithms with a focus on human error reduction. We're also looking at the cost of AI and any progress in the reimbursement landscape for algorithm utility.

Covid Begins Early Peak in Back-to-School Season

With Fall weather comes the now annual uptick in Covid-19 hospitalizations. U.S. Covid-19 hospitalizations have been climbing since early July (6,464 hospital admissions the week of July 8) and have since tripled to 18,871 hospitalizations for the week ending September 2.

If past trends continue, then Covid-19 hospitalizations will peak in mid-September and will be in full retreat until Holiday Season 2023 (mid-November through January 1).

U.S. Weekly Hospital Admissions for Covid-19
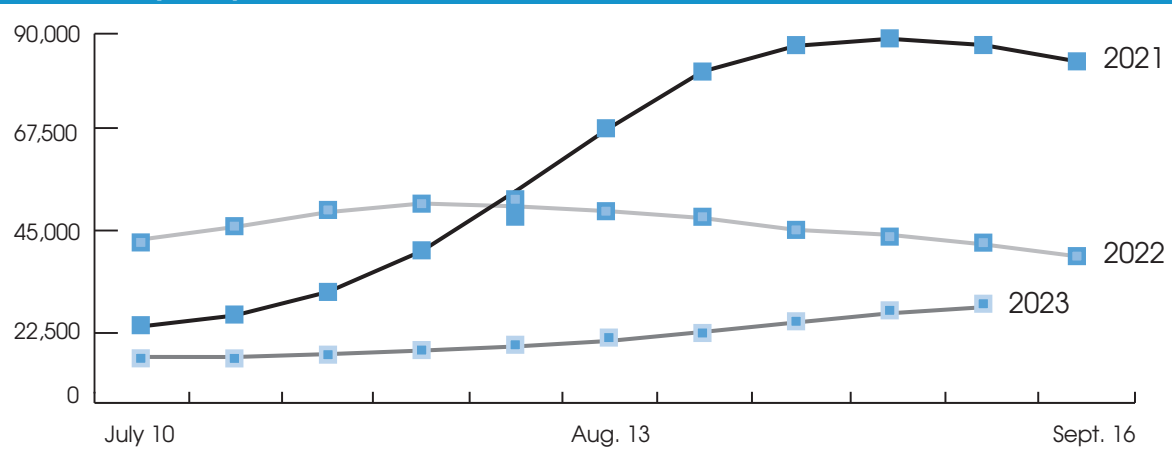
Lawsuit Calls Everlywell's Food Sensitivity Tests "Snake Oil"

A proposed class action filed by Massachusetts resident Joyce Toth alleges Everlywell Food Sensitivity Tests are "worthless" and cannot identify adverse food sensitivities as advertised. Toth is being represented by the whistleblower law firm Tycko & Zavareei (Washington, DC), which filed the case in Massachusetts District Court against Everly Well Inc. and its parent company Everly Health Inc. (dba Everlywell).

Toth purchased the 96-food version of the Everlywell Food Sensitivity Test online for $119.99 in July 2022. According to the suit, the test measures the level of immunoglobulin G antibodies in the blood, which only tells a person if they ate a food recently. Toth claims that the test results wrongly indicated that she was sensitive to eggs (which she is not) and that she was not allergic to shellfish (which she is). In addition, Toth claims that consumers are not told until after they purchase their tests that they cannot receive their test results until they agree to allow Everlywell to retain and sell their medical information.

"Ultimately, Defendants are selling expensive snake oil and earning massive profits from the sale, while also acquiring for no cost valuable private consumer data, which they claim to have a right to use for their own purposes and profit," the suit summarizes.

Walgreens to Pay $44 Million to Theranos Customers

Walgreens Boots Alliance (Deerfield, IL) has agreed to a $44 million settlement to resolve class-action claims related to its partnership with Theranos.

The proposed settlement, which needs court approval, will provide consumers who participated in the lawsuit with "approximately double their out-of-pocket damages," lawyers for plaintiffs said in a court filing in federal court in Phoenix on September 6.

The class-action lawsuit accusing Walgreens of being "willfully blind" to the fraudulent company, which claimed to offer hundreds of lab tests with only a few drops versus vials of blood thanks to its proprietary technology, called Edison. Walgreens partnered with Theranos in 2013 and installed sample collection kiosks in 40 stores in Arizona and one store in Palo Alto, California, without validating its technology.

Theranos formally dissolved nearly three years after *The Wall Street Journal* uncovered discrepancies about the once-valued $9 billion company in 2015. Walgreens ended its partnership with Theranos in 2016 and shut down all testing locations.

Although Walgreens agreed to settle the class-action lawsuit against it rather than go to trial, the pharmacy chain maintains it too was duped by Theranos.

Elizabeth Holmes, age 39, founder and CEO of Theranos, was convicted of fraud in 2022 and sentenced to 11.25 years in prison. Ramesh "Sunny" Balwani, 58, former Theranos President, was also found guilty and is serving a 13-year sentence.

Labcorp Offering Direct-to-Consumer Menopause Test

Labcorp is now marketing a menopause test panel directly to consumers through its website www.ondemand.labcorp.com. The panel includes four hormone tests (estradiol, follicle-stimulating hormone (FSH), luteinizing hormone and progesterone). The cost to consumers is $139, which includes a $6.50 fee paid to PWNHealth to review test orders. After purchase, consumers must provide a blood specimen at one of Labcorp's 2,000+ patient service centers nationwide, including over 400 Walgreens locations. Results are provided online in about 6-10 days after Labcorp has received the specimen.

THE COVID TESTING BOOM & BUST IS OVER (*cont'd from page 1*)

Among five national clinical labs (Quest Diagnostics, Labcorp, Sonic Healthcare USA, BioReference and Enzo), combined revenue fell by 7.4% (after adjusting for acquisitions).

Meanwhile, among 19 specialty and genetic testing labs, combined pro-forma revenue increased by 3%.

The fastest-growing lab companies included:

Castle Biosciences

Pro-forma revenue growth was fastest at Castle Biosciences (Friendswood, TX), up 49% to $92.2 million for the six months ended June 30, 2023. Net loss for the six-month period was $48 million vs. a net loss of $26.3 million a year earlier.

Castle's revenue is primarily generated by its DecisionDx-Melanoma risk stratification gene expression profile test. This test predicts the risk of metastasis or recurrence for patients diagnosed with invasive cutaneous melanoma. In the first half of 2023, Castle performed 16,180 DecisionDx-Melanoma tests, up 23% from 13,148 tests in the first half of 2022. The Medicare rate for DecisionDx-Melanoma is $7,193.

Castle also markets DecisionDx-SCC—a risk stratification test for cutaneous squamous cell carcinoma. In the first half of 2023, Castle performed 5,092 DecisionDx-SCC tests, up 105% from 2,486 tests. The Medicare rate for DecisionDx-SCC is $8,500.

Castle's third highest volume test is IDgenetix, which analyzes 15 genes to help doctors make prescription recommendations for patients with depression. In the first half of 2023, Castle performed 4,831 IDgenetix tests, up 484% from 827 tests. The Medicare rate for IDgenetix is currently $917.

Exagen Inc.

Exagen Inc. (Vista, CA) grew its first-half 2023 revenue by 41% to $25.4 million. Net loss for the six-month period was $12.7 million vs. a net loss of $24.9 million a year earlier.

Exagen's lead testing product is AVISE CTD—an autoimmune rheumatic disease test panel designed to aid physicians in the differential diagnosis of systemic lupus erythematosus. Exagen performed 75,061 AVISE CTD tests in the six months ended June 30, 2023, up 14% from 65,822 tests delivered in the same 2022 period. The Medicare rate for AVISE CTD is $1,067.

Interpace Biosciences

Interpace Biosciences (Parsippany, NJ) grew its first-half 2023 revenue by 36% to $20.9 million. Net income for the six-month period was $526,000 vs. a net loss of $6.2 million a year earlier. The revenue increase was driven by increased test volumes for the company's molecular oncology tests as well as improved collections.

Guardant Health

Guardant Health (Palo Alto, CA) grew its first-half 2023 revenue by 30% to $266 million. Net loss for the six-month period was $206 million vs. a net loss of $353 million a year earlier.

Guardant's lead testing product is Guardant360—a liquid biopsy blood test that analyzes 70+ genes to guide cancer patient treatment, including for breast and lung cancer. The average selling price across all payers for Guardant360 is between $2,600 and $2,700.

Total tests performed for clinical clients increased by 46% to 82,600 for the six months ended June 30, 2023. Total tests for biopharmaceutical customers increased by 16% to 12,850.

Revenue Growth at 24 Publicly Traded Lab Companies ($000)

Company	First-Half 2023	First-Half 2022	Reported Change	Estimated Pro Forma Change*
Quest Diagnostics (lab testing only)	$4,527,000	$4,925,000	-8.1%	-8.4%
Labcorp (lab testing only)	4,723,600	4,709,500	0.3%	-1.8%
Sonic Healthcare USA[1]	693,500	735,800	-5.7%	-10.0%
Opko/BioReference Labs	259,420	473,402	-45.2%	-45.2%
Enzo Clinical Labs (lab testing only)[2]	17,446	42,304	-58.8%	-58.8%
Total, 5 National/Clinical Labs	**$10,220,966**	**$10,886,006**	**-6.1%**	**-7.4%**
Exact Sciences	1,224,543	1,008,211	21.5%	21.5%
Natera	503,160	392,333	28.2%	28.2%
Myriad Genetics	364,700	344,200	6.0%	6.0%
NeoGenomics	284,137	242,241	17.3%	17.3%
Guardant Health	265,864	205,243	29.5%	29.5%
Invitae Corp.	237,888	260,313	-8.6%	-8.6%
Veracyte	172,744	140,647	22.8%	22.8%
CareDx	147,563	160,050	-7.8%	-7.8%
Fulgent Genetics	134,021	445,609	-69.9%	-72.0%
Castle Biosciences	92,175	61,690	49.4%	49.0%
GeneDx	91,845	90,110	1.9%	1.9%
ProPhase Labs	32,520	76,623	-57.6%	-57.6%
Exagen Inc.	25,367	18,000	40.9%	40.9%
Biodesix	20,928	17,498	19.6%	19.6%
Interpace Biosciences	20,853	15,318	36.1%	36.1%
Psychemedics	11,396	13,021	-12.5%	-12.5%
Dermtech	7,457	7,951	-6.2%	-6.2%
Aspira Women's Health	4,807	3,959	21.4%	21.4%
Biocept Inc.	1,262	25,763	-95.1%	-95.4%
Total, 19 Specialty/Genetic Labs	**$3,643,230**	**$3,528,780**	**3.2%**	**3.0%**
Grand Total, All 24 Lab Companies	**$13,864,196**	**$14,300,668**	**-3.1%**	**-4.1%**

*Pro forma change is estimated by *Laboratory Economics* after adjustments for acquisitions and currency fluctuations.

[1]Sonic Healthcare USA revenue is for the six months ended June 30, 2023, at constant exchange rate of 1 Australian Dollar equal to 0.67 U.S. Dollar.   [2]Enzo's revenue is for lab services only for six months ended April 30, 2023.

Source: *Laboratory Economics* from company reports

Lab Stocks Down 7% Year-to-Date In 2023

Twenty-four lab stocks have dipped by an unweighted average of 7% year to date through September 15. In comparison, the S&P 500 Index is up 16% year to date. The top-performing lab stocks thus far in 2023 are Exact Sciences, up 55%; NeoGenomics, up 46%; and Opko Health, up 31%. Labcorp shares are flat (after adjusting for spinoff of Fortrea) and Quest Diagnostics is down 19%.

Company (ticker)	Stock Price 9/15/23	Stock Price 12/30/22	2023 Price Change	Enterprise Value ($ millions)	Revenue for Trailing 12 mos. ($ millions)	Enterprise Value/ Revenue
Exact Sciences (EXAS)	$76.68	$49.51	55%	$15,780	$2,301	6.9
NeoGenomics (NEO)	13.46	9.24	46%	1,950	552	3.5
Opko Health (OPK)	1.64	1.25	31%	1,460	868	1.7
Natera (NTRA)	51.50	40.17	28%	5,820	931	6.3
Aspira Women's Hlth (AWH)[1]	5.98	4.95	21%	59	9	6.6
Myriad Genetics (MYGN)	16.61	14.51	14%	1,440	699	2.1
Interpace Biosciences (IDXG)	1.15	1.04	11%	61	37	1.6
Guardant Health (GH)	29.53	27.20	9%	3,610	510	7.1
Veracyte (VCYT)	25.05	23.73	6%	1,650	329	5.0
Sonic Healthcare (SHL.AX)*	31.02	29.97	4%	17,010	8,170	2.1
DermTech Inc. (DMTK)	$1.81	$1.77	2%	30	14	2.1
Exagen (XGN)	2.43	2.40	1%	35	53	0.7
Labcorp (LH)	201.65	202.30	0%	22,260	14,881	1.5
Fulgent Genetics (FLGT)	29.67	29.78	0%	65	307	0.2
Enzo Biochem (ENZ)	1.30	1.43	-9%	84	71	1.2
Quest Diagnostics (DGX)	126.22	156.44	-19%	19,110	9,488	2.0
Psychemedics (PMD)	3.89	4.90	-21%	23	24	1.0
Castle Biosciences (CSTL)	17.30	23.54	-27%	253	168	1.5
CareDx (CDNA)	7.92	11.41	-31%	183	309	0.6
Biodesix (BDSX)	1.39	2.30	-40%	137	42	3.3
GeneDx (formerly Sema4)[2]	4.38	8.71	-50%	32	236	0.1
ProPhase Labs (PRPH)	4.56	9.63	-53%	83	79	1.1
Invitae (NVTA)	0.81	1.86	-56%	1,480	494	3.0
Biocept (BIOC)[3]	1.67	15.90	-89%	9.3	1.4	6.7
Totals & Averages			-7%	$92,623	$40,572	2.3

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

Northwestern Medicine is at Top for Laboratory Outreach Revenue

Northwestern Medicine (Chicago, IL) operates the largest lab outreach business as measured by Medicare Clinical Laboratory Fee Schedule (CLFS) and Pathology Physician Fee Schedule (PFS) fee-for-service payments in 2022. Northwestern Medicine received $30.7 million in Medicare CLFS payments and $1.6 million in pathology PFS payments for a total of $32.3 million in payments in 2022. Northwestern Medicine's largest outreach labs are based at Central DuPage Hospital (Winfield, IL) and Northwestern Memorial Hospital (Chicago, IL).

Top 20 Health Systems by Medicare CLFS and Pathology PFS Payments for 2022

Health System	Total Medicare CLFS Payments	Total Medicare Pathology PFS Payments	Grand Total
Northwestern Medicine (Chicago, IL)	$30,717,563	$1,591,820	$32,309,383
CommonSpirit Health (Englewood, CO)	28,888,956	3,340,105	32,229,061
Trinity Health (Livonia, MI)	29,238,380	1,805,363	31,043,743
Ascension Health (Saint Louis, MO)	24,439,293	866,989	25,306,282
Mass General Brigham (Boston, MA)	20,318,144	2,564,476	22,882,620
Cleveland Clinic Health Sys. (Cleveland, OH)	21,042,872	690,365	21,733,237
Corewell Health (Grand Rapids, MI)	19,470,679	810,688	20,281,367
Providence (Renton, WA)	18,014,986	1,353,542	19,368,528
Northshore-Edward-Elmhurst Health (Evanston, IL)	18,059,053	1,080,350	19,139,403
Advocate Health Care (Charlotte, NC)	17,952,517	1,075,494	19,028,011
Penn Medicine (Philadelphia, PA)	15,092,182	3,054,774	18,146,956
University of Texas System (Dallas, TX)	9,258,786	7,828,509	17,087,295
Beth Israel Lahey Health (Boston, MA)	16,008,616	1,075,112	17,083,728
University of California Health (Oakland, CA)	14,668,738	2,084,440	16,753,178
Community Health Systems (Franklin, TN)	14,859,298	506,637	15,365,935
AdventHealth (Altamonte Springs, FL)	14,907,704	405,413	15,313,117
Yale New Haven Health (New Haven, CT)	14,629,921	550,667	15,180,588
HCA Healthcare (Nashville TN)	14,207,683	447,471	14,655,154
University of Pittsburgh Medical Center (Pittsburgh, PA)	12,459,064	1,555,523	14,014,587
Bon Secours Mercy Health (Cincinnati, OH)	13,070,659	374,519	13,445,178
Grand Totals for all Health Systems	**$1,535,103,608**	**$115,832,357**	**$1,650,935,965**

Source: CMS/Medicare fee-for-service payments for clinical lab and pathology services in 2022