# LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

# PathNet Seeks to Bring Digital Pathology & AI to Local Pathologists

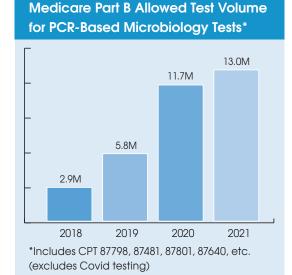
The digital pathology lab startup PathNet Inc. (Little Rock, AR) and three of its pathology group clients are merging to create one full-service pathology lab company. The three groups are Connect Pathology (Lehi, UT), StarPath (Long Island, NY) and TruCore Pathology (Little Rock, AR). The combined organization will employ six pathologists utilizing 100% digital pathology with artificial intelligence algorithms for quality control. For *LE's* interview with Hillel Kahane, MD, Co-owner and Director of Uropathology at PathNet, *see pages 5-6*.

# Rapid Growth for PCR-Based Microbiology Tests

Everyone knows that genetic test volumes are growing fast, but PCR-based microbiology

Medicare Part B Allowed Test Volume

based microbiology testing (excluding Covid) is growing even faster. During the three-year period from 2018-2021, Medicare Part B allowed claims for PCR-based microbiology tests grew by 59% per year. This compares with 18% per year for genetic tests, -1% for anatomic pathology, -2% for routine clinical lab tests and -10% for toxicology over the same three-year period. Full details on page 4.



Source: Laboratory Economics from CMS

# Labcorp to Buy Enzo Clinical Lab

Labsorp has agreed to acquire the assets of Enzo Biochem's clinical lab division (aka Enzo Clinical Labs) for \$156 million in cash. The purchase price is equal to approximately three times Enzo Clinical Labs' revenue of \$50 million for the 12-month period ended January 31, 2023. The sale to Labcorp follows a drawn-out battle between Enzo's founders and a group of investors led by Harbert Discovery Fund (Birmingham, AL). Continued on page 2.

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#### LABCORP TO BUY ENZO CLINICAL LAB (cont'd from page 1)

Harbert Discovery Fund had argued that Enzo Biochem was being poorly managed to the detriment of shareholders. Harbert led a successful proxy fight to vote in new board members and management at Enzo (see LE, April 2022) early last year.

Like many other labs, Enzo Clinical Labs saw its revenue skyrocket and then plummet because of

Covid-19 PCR testing (see graph).

Enzo operates a 43,000-square-foot CAP-accredited lab in Farmingdale, NY (Long Island) and two small stat labs in New York City and Connecticut. It has approximately 300 lab employees and 30 patient service centers in New Jersey, New York and Connecticut. Its highest volume tests include CPT 80053 (Comprehensive metabolic panel), 85025 (complete blood count) and 80061 (lipid panel).

Enzo Clinical Labs recorded a pretax loss of \$14.8 million in the six months ended January 31, 2023 versus a pretax gain of \$6.6 million in the same period a year earlier; revenue was \$20 million, down 54% from \$43.4 million.

Assuming the deal is finalized, Labcorp is likely to consolidate most of Enzo's test volume into its regional lab in Raritan,



New Jersey—about 90 miles west of Enzo's main lab in Long Island.

"We look forward to integrating these capabilities through a smooth and seamless transition of services while maintaining a presence on Long Island with testing and service teams," according to Bill Haas, Senior Vice President of Labcorp Diagnostic's Northeast Division.

#### Financial Results for Enzo Clinical Labs Division (\$ 000)

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Enzo Clinical Labs	6 mos. ended January 31, 2023	6 mos. ended January 31, 2022	% Chg				
Total revenue	\$19,997	\$43,415	-54%				
Non-Covid testing revenue	18,797	20,839	-10%				
Covid testing revenue	1,200	22,576	-95%				
Cost of revenue	20,545	23,789	-14%				
Research & development expense	603	96	528%				
Selling, general & administrative expense	13,493	12,812	5%				
Legal fees	171	205	-17%				
Operating income	-14,815	6,513	NA				
Pretax income	-14,806	6,562	NA				
# Lab Employees	~300	~295	2%				

Source: Enzo Biochem



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The New York City metropolitan area, including northern New Jersey, is the largest metropolitan statistical area in the United States with 20 million residents as of 2021. This makes it the largest physician lab services market as well, which *Laboratory Economics* estimates at \$2.5 billion per year. Below we summarize the largest lab players in the NYC market.

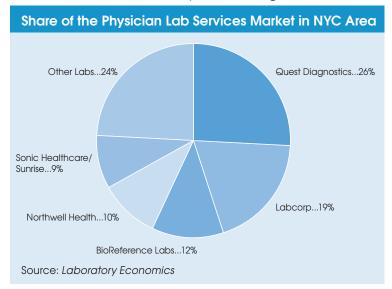
**Quest Diagnostics** operates a regional lab in Clifton, New Jersey (northern NJ) and has approximately 225 patient service centers in the New York City area. Estimated annual revenue from physician office clients is \$650 million. In late 2020, Quest entered into an agreement to manage the lab operations and provide reference testing to 11 hospitals that are part of Hackensack Meridian Health (HMH) in northern New Jersey. Approximately 30% of HMH's testing volume has been shifted to Quest's lab in Clifton.

**Labcorp** has a regional lab in Raritan, New Jersey (northern NJ) and more than 100 PSCs in the New York City area. In August 2022, Labcorp acquired the assets of RWJBarnabas Health's clinical lab outreach business. After it completes its acquisition of Enzo Clinical Labs, Labcorp's annual revenue from physician office clients in NYC will be an estimated \$475 million.

**BioReference Labs**, which is owned by OPKO Health, operates a major lab in Elmwood Park, New Jersey (northern NJ) and has 66 PSCs in the New York City area. Estimated annual revenue from the physician office market is \$300 million.

**Northwell Health** (New Hyde Park) is New York's largest healthcare system. It operates an independent lab (dba Northwell Health Labs) based in Long Island and has 40 PSCs. Northwell Health also owns an independent lab (dba Apex Laboratory) focused on the home health and nursing home markets. Estimated annual revenue from the physician office market is \$250 million.

**Sonic Healthcare** owns a major lab in Long Island (dba Sunrise Medical Labs) and has more than 50 PSCs in the New York City area. Sonic generates an estimated \$225 million in revenue from



physician office clients in the NYC area. In 2017, Sonic and NYU Langone Health formed a joint venture (dba NYU Langone Diagnostics) aimed at insourcing outreach lab services for NYU's more than 2,000 affiliated physicians.

Other independent labs with a big presence in the physician office lab services market in New York City area include Accu Reference Medical Lab (Linden, NJ), Accurate Diagnostics Labs (South Plainfield, NJ) and Lenco Diagnostic Labs (Brooklyn, NY).

#### RAPID GROWTH FOR MICROBIOLOGY TEST VOLUMES (cont'd from page 1)

The top three fastest-growing clinical lab tests are all PCR-based microbiology tests. CPT 87801 (Infectious agent detection by nucleic acid (DNA or RNA), multiple organisms; amplified probe(s) technique) is at the top of the list with Medicare Part B test volume growth of 82% per year between 2018 and 2021.

CPT 87481 (Infectious agent detection by nucleic acid (DNA or RNA); Candida species, amplified probe technique) had Part B test volume growth of 79% per year.

CPT 87798 (Infectious agent detection by nucleic acid (DNA or RNA), not otherwise specified; amplified probe technique, each organism) had Part B test volume growth of 73% per year.

The growth in PCR-based microbiology testing is likely to continue, as many labs have recently shifted their excess Covid-19 PCR testing capacity into microbiology testing for urinary tract infections and sexually transmitted diseases.

Top 25 Fastest-Growing Clinical Lab Tests by Medicare Part B Allowed Volume, 2018-2021

•		2021	2018	
СРТ		Part B	Part B	3-Year
Code	Category & Short Description	Allowed Tests	Allowed Tests	CAGR
87801	Microbiology: Detect agent multi DNA ampli probe(s)	668,184	111,652	81.6%
87481	Microbiology: Candida DNA ampli probe	1,065,253	186,596	78.7%
87798	Microbiology: Detect agent NOS DNA ampli probe	5,983,697	1,165,255	72.5%
86334	Immunology: Immunofixation electrophoresis; serum	1,303,122	748,404	20.3%
84165	Chemistry: Protein E-phoresis; serum	1,929,894	1,187,382	17.6%
87799	Microbiology: Detect agent NOS DNA quantitative	352,489	218,802	17.2%
86335	Immunology: Immunofixation electrophoresis; other fluids	228,416	145,384	16.3%
84166	Chemistry: Protein E-phoresis; urine	303,508	201,074	14.7%
83520	Chemistry: Immunoassay NOS non-antibody	789,692	559,702	12.2%
85379	Hematology & Coagulation: D-dimer; quantitative	159,407	115,875	11.2%
87661	Microbiology: Trichomonas vaginalis ampli probe	176,414	133,636	9.7%
84466	Chemistry: Transferrin	353,751	274,364	8.8%
87591	Microbiology: Neisseria gonorrhoeae, ampli probe	240,373	199,046	6.5%
84144	Chemistry: Progesterone	196,869	163,440	6.4%
84146	Chemistry: Prolactin	221,986	185,234	6.2%
86146	Immunology: Beta 2 glycoprotein antibody	157,259	131,370	6.2%
87491	Microbiology: Chlamydia trachomatis, ampli probe	242,111	202,548	6.1%
86480	Immunology: Tuberculosis test	221,042	190,330	5.1%
84270	Chemistry: Sex hormone binding globulin (SHBG)	322,912	278,601	5.0%
82652	Chemistry: Vitamin D	198,980	172,457	4.9%
84402	Chemistry: Free testosterone	376,582	326,641	4.9%
82330	Chemistry: Calcium	162,891	145,485	3.8%
86235	Immunology: Extractable nuclear antigen (ENA)	1,573,804	1,426,971	3.3%
82670	Chemistry: Total estradiol	364,388	331,989	3.2%
83970	Chemistry: Parathyroid hormone (PTH)	1,649,551	1,513,769	2.9%
	Total for Top 25 Tests	19,242,575	10,316,008	23.1%

Note: Includes clinical lab tests with a minimum 100,000 allowed test volume in 2018 (excluding Covid, genetic tests and anatomic pathology)

Source: Laboratory Economics from CMS

#### PATHNET SEEKS TO BRING DIGITAL PATHOLOGY & AI (cont'd from page 1)



Hillel Kahane, MD

Hillel Kahane, MD, is a board-certified uropathologist with more than 30 years of experience in the commercial lab industry. Prior to founding StarPath, Dr. Kahane was Chief Medical Officer at Acupath Laboratories (2018-2020), Medical Director at Bostwick Laboratories (2007-2018) and Executive Medical Director for Uropathology at Dianon (1993-2007). Over the course of his career, Dr. Kahane has signed out over 1 million prostate needle biopsies. Below we summarize his views on PathNet and the future of digital pathology and AI.

#### What's the benefit of merging into one pathology lab company?

Economies of scale will help lower the cost for billing and collection, marketing and accounting services.

In addition, PathNet has begun to build out a dedicated management team. Last year, for example, PathNet hired Jason Camilletti as its new Chief Executive Officer. He took over the role from the PathNet's founder, Matthew Leavitt, MD, who remains Chairman. Jason was previously Commander of the 48th Fighter Wing of the U.S. Air Force, where he managed the largest U.S. fighter jet mission and Air Force Hospital in Europe.

#### How big is PathNet?

Once the merger is complete, PathNet will have six employed pathologists and another three contracted pathologists. Last year, PathNet processed a total of 41,000 patient cases, including 18,500 prostate cases and 22,500 bladder, urine cytology, gastrointestinal and dermatopathology cases. We're in the process of expanding our presence in GI and dermatopathology.

#### Can you describe the workflow process at PathNet?

Referring physicians place their biopsy cores in a specimen collection cassette ("BxBoard") made by Lumea (Lehi, UT). Lumea's BxBoard holds six cores per cassette. The BxBoard cassettes are shipped by FedEx or UPS to PathNet's histology labs in either Little Rock, Arkansas (for East Coast) or Lehi, Utah (for West Coast).

Slides are prepared using Lumea's BxChip which enables up to 18 cores to be placed on one slide while maintaining tissue orientation. Slides are then digitized using scanners from Leica (Aperio GT450 DX or Aperio AT2).

Slide images are made available to PathNet's pathologists within 24 hours via the Cloud for professional interpretation on their computer monitors or iPad Pro tablets. We're 100% digital with result reports made in under 24 hours.

#### How do you use AI algorithms?

Once I have completed my review of all the cores, I turn on an AI software algorithm to see what it highlights as being suspicious for cancer versus my annotations and Gleason Scores. The AI is very good at picking out small cancers that might otherwise have been undetected.

#### Which AI software is used by PathNet?

Over the past two years, PathNet's pathologists have been "test driving" AI algorithms developed by a variety of vendors, including Aira-Matrix, Deep Bio Inc., Paige, Google's Verily, ContextVision, and others. They all work well—the better ones provide Gleason Scores (for predicting prognosis and guiding therapy).



Right now, we are using AI only for prostate cancer, but working with some AI companies on developing algorithms for other cancer types.

#### How often does the AI differ from your initial diagnosis?

Roughly less than half a percent, but this can vary greatly depending on the individual pathologist. For example, a study conducted by Ibex Medical Analytics at France's largest pathology lab network (Medipath) showed that between 5% and 12% of benign cases were either cancer or suspicious for cancer in a retrospective study after AI. [See Performance of an AI-Based Cancer Diagnosis System in France's Largest Network of Pathology Institutes; Presented at the European Congress of Pathology 2019.]

In those cases where there is a discrepancy, I go back and re-check the digital image. It can be a humbling experience, but it's helping me find more cancers.

#### How much does AI cost?

That's the million-dollar question. There are no CPT codes for AI and it's still very early in terms of pathologist adoption.

#### What are the potential pitfalls of using AI?

Pathologists will need to be careful not to over-rely on it. Knowing that a second set of eyes will be double-checking all their slides might cause a pathologist to not look as carefully as they should. We're trying to figure out how AI might influence or bias the pathologists that use it.

#### How will digital pathology and AI change malpractice insurance?

It improves accuracy so malpractice insurance rates for pathologists using it should be lower.

#### Is PathNet using digital pathology and AI as a marketing tool?

Yes. Urologists want to know their pathologist is using cutting-edge technology.

But it may be even better for attracting pathologists to join PathNet. They can read cases on their iPads from home with flexible hours. It's also very appealing to young pathologists who want to get experience with AI since it's cutting edge and could help with their career development.

#### Will AI replace the need for the human eye?

Never. I liken it to the use of AI in flying commercial airlines. AI is used in every aircraft for takeoffs and landings, yet no passenger would ever board a plane without a pilot.

AI in pathology is inevitable.

The real competition will be between those pathologists that embrace AI assistance and those that don't.

#### **PathNet Pathology Practices**

Pathology Group	Specialty	Employed Pathologists
Connect Pathology (Lehi, UT)	general pathology, histology lab	Jared Szymanski, DO* Anthony Perry, MD*
StarPath (Long Island, NY)	prostate biopsies	Hillel Kahane, MD*
TruCore Pathology (Little Rock, AR)	prostate biopsies, dermatopathology, histology lab	Adam J. Cole, MD* Alicia Schnebelen, MD Michele Cox, MD

\*Co-owners of PathNet

Source: PathNet Inc.



# OIG Okays Patient Gift Cards for Cologuard Test Sample Returns

On March 29, the U.S. Department of Health and Human Services Office of Inspector General (OIG) issued Advisory Opinion 23-03 stating that giving some patients \$75 gift cards in exchange for returning their test samples would not violate anti-kickback law.

The Advisory Opinion was clearly issued in response to a question about Exact Sciences' \$75 gift card program used to encourage patients to return their Cologuard stool sample collection kits (see *LE*, January 2023).

This favorable opinion is noteworthy because OIG typically disfavors arrangements under which providers distribute gift cards to incentivize patients to obtain federally reimbursable services.

The OIG concluded that the gift card program meets the requirements of the exception to the definition of remuneration for incentives given to beneficiaries to promote the delivery of preventive care. OIG noted that the Cologuard screening test is included in the U.S. Preventive Services Task Force's (USPSTF's) Guide to Clinical Preventive Services.

Meanwhile, a whistleblower lawsuit filed by retired pathologist Niles Rosen, MD against Exact Sciences in June 2019 is slowly making its way through the discovery phase. Rosen claims that Exact's gift card program, which has been discontinued, violated anti-kickback and false claims laws.

# Genotox to Pay \$5.9M to Settle Unnecessary Drug Testing Allegations

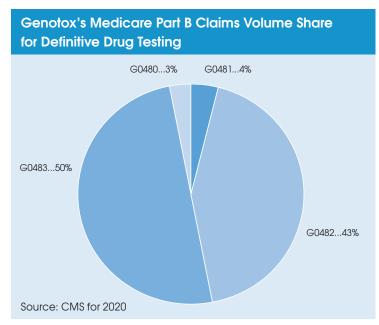
Genotox Laboratories (Austin, TX) has reached an agreement with the federal government to resolve False Claims Act and Anti-Kickback Statute violations, stemming from allegations related to unnecessary drug testing claims, the U.S. Department of Justice announced on April 4.

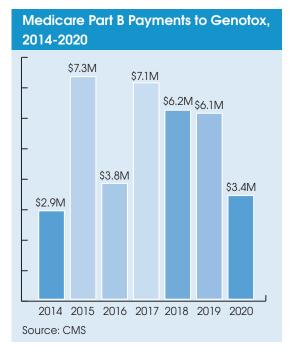
The agreement was signed by Matthew McCarty, MD, Founder and Chief Executive Officer of Genotox.

The federal government alleged that, between 2014 and 2020, Genotox made illegal payments to 1099 sales contractors and marketing companies in exchange for those entities facilitating or recommending Genotox to conduct lab tests. Moreover, Genotox submitted false reimbursement re-

quests to the Medicare and Tricare programs for claims between 2014 and 2022 related to unreasonable testing and unnecessary standing orders for drug testing.

Genotox also admitted that it used order forms with "custom profiles" and typically billed payers at the highest amount possible (i.e., G0482 and G0483) for definitive drug tests. For example, Genotox billed Medicare for either G0482 (def 15-21 drug classes; \$199) or G0483 (def 22+ drug classes; \$247) for 93% of its definitive drug testing claims in 2020.





The \$5.9 million settlement amount was based on Genotox's ability to pay. It compares with \$36.8 million of Medicare Part B payments made to Genotox between 2014 and 2020.

In addition to the \$5.9 million monetary penalty, Genotox entered into a five-year Corporate Integrity Agreement (CIA) with the Department of Health and Human Services Office of Inspector General. The CIA requires Genotox to maintain a compliance program, implement a risk management program and hire an Independent Review Organization to oversee its Medicare and Medicaid claims submissions.

The civil settlement includes the resolution of claims brought under the *qui tam* or whistleblower provisions of the False Claims Act by Alex DiGiacomo, Genotox's former billing manager. He worked there for approximately five years before resigning in June

2020. As part of the \$5.9 million settlement, DiGiacomo will receive approximately \$1 million (17%).

This settlement demonstrates the continued government scrutiny on marketing firms and independent contractor sales representatives for certain commission-based payments in the lab setting, notes Myla Reizen, Partner at K&L Gates LLP (Miami, FL). It is interesting that the initial whistleblower complaint alleged certain conduct violated both the AKS and EKRA. This also highlights the government focus on urine drug testing services in the lab industry, adds Reizen.

# Versant Diagnostics and In-Office Pathology Team Up

Tersant Diagnostics (Grapevine, TX) has signed an agreement with In-Office Pathology LLC (Nantucket, MA). Versant will offer professional pathology services to IOP's network of in-office labs, and IOP will build histology labs at select Versant Diagnostics specialty clinics and physician practices.

IOP was founded by Joe Plandowski and Bernie Ness in 2004. Over the past 18 years, IOP has developed in-office histology labs at 99 specialty groups in 30 states. The majority of these labs are located at gastroenterology practices and others are located at urology, dermatology and podiatry groups.

Under the new agreement, IOP's lab clients will continue to directly bill payers for global lab services, including professional and technical fees. Versant's pathologists will provide professional interpretations at a negotiated fee. Initially, Versant is expected to provide professional services to IOP's lab clients in the greater Chicago area. In the future, new and existing IOP lab clients from around the country will have the option of installing slide scanners so that Versant's pathologists can provide professional interpretations from digital images.

Plandowski says that finding and hiring pathologists has become one of IOP's biggest challenges. He notes that after a pandemic slowdown in 2020-2021, IOP has since signed seven new clients, including three gastroenterology groups, three podiatry groups and one derm group.

Versant is a startup pathology company founded by Ven Aduana, MD, Jim Billington and Brian Carr in 2021 (see *LE* November 2021). Versant, which currently has 15 pathologists, has \$100 million in financing (both equity and debt) from Iron Path Capital (Nashville, TN). Versant is acquiring pathology practices and then seeking to add volume through the use of digital pathology.



# Average Pathologist Compensation Up 2.7% to \$357,384

Pathologists were among the top 10 specialties with the largest increase in average compensation in 2022, according to a survey by Doximity (San Francisco, CA).

Pathologist compensation rose by 2.7% to an average of \$357,384 in 2022. Emergency medicine physicians reported the highest increase in compensation, up 6.2% to \$385,554.

The physician specialties with the highest average compensation in 2022 were neurosurgery — \$788,313, thoracic surgery — \$706,775, orthopedic surgery — \$624,043, and plastic surgery — \$571,373.

Doximity is an online networking service for medical professionals. The platform offers its members curated medical news, telehealth tools, and case collaboration. The Doximity compensation survey included responses from over 31,000 full-time U.S. physicians in 2022.

The top 10 specialties with the LARGEST increase in average annual compensation

Specialty	Compensation Growth	2022 Average Compensation
Emergency Medicine	6.2%	\$385,554
Pediatric Infectious Disease	4.9%	\$221,126
Pediatric Rheumatology	4.2%	\$226,186
Preventive Medicine	4.0%	\$275,068
Pulmonology	3.9%	\$400,650
Pediatric Cardiology	3.4%	\$325,595
Thoracic Surgery	3.2%	\$706,775
Pathology	2.7%	\$357,384
Plastic Surgery	2.6%	\$571,373
Pediatric Emergency Medicine	2.6%	\$287,635

Source: Doximity 2023 Physician Compensation Report

# Medi-Cal Rate Survey Gives Clues to Private-Payer Trends

The California Department of Health Care Services will announce its new Medi-Cal fee-for-service lab and pathology rates within a month or two. CDHCS's Medi-Cal rates are based on a triennial weighted average-rate calculation from a survey of private-payer rates from independent labs and hospitals in California.

The latest calculation will be based on third-party payer rate data collected from calendar year 2021 (pursuant to Welfare and Institutions Code section 14105.22) and will become effective July 1, 2023. It's of great interest to the lab industry because it gives a clue as to how the next national survey of private payer rates under PAMA might turn out.

Under PAMA, labs are currently scheduled to turn in their private-payer data from 2019 to CMS in early 2024. This information will be used to set Medicare CLFS rates for 2025.

Meanwhile, Medi-Cal fee-for-service payments to labs and pathologists have been steadily falling since 2012. This has been primarily due to a shift in Medi-Cal membership to managed care plans. Medi-Cal managed care plans are paid on a capitated basis, and they manage member care and negotiate their own rates with their contracted providers. As of February 2023, Medi-Cal served 15.5 million members, including 13.3 million in managed care plans and 2.2 million in traditional fee-for-service.



#### **Top 20 Medi-Cal Laboratories**

The largest Medi-Cal lab provider is Quest Diagnostics, which received \$24.1 million of Medi-Cal FFS payments in 2022, down 9.4% per year from \$32.5 million in 2019, according to data from the California DHCS.

Planned Parenthood, which tests for sexually transmitted diseases, received \$18.5 million, down 14.5% per year from \$29.6 million in 2019.

The Genetic Disease Screening Program (GDSP) of the California Department of Public Health was the third largest, with \$17.3 million, down 14.4% from \$27.6 million in 2019. The Genetic Disease Screening Program provides prenatal and newborn testing services to Medi-Cal recipients.

LabCorp received \$8.6 million of Medi-

\$314 \$298 \$265 \$242 \$207 \$208 \$207 \$214 \$193 \$199 \$191 \$2012 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022 \*Lab test expenditures are for Medi-Cal fee-for-service enrollees only Source: California DHCS

Cal payments in 2022, down 5.6% per year from \$10.3 million in 2019.

Top 20 Medi-Cal Fee-for-Service Laboratories in 2022

Provider	2022 Reimbursements Paid (FFS Only)	2019 Reimbursements Paid (FFS Only)	3-Year CAGR
Quest Diagnostics	\$24,144,246	\$32,469,925	-9.4%
Planned Parenthood	18,533,472	29,634,204	-14.5%
CDPH Genetic Disease Branch	17,277,356	27,573,854	-14.4%
LabCorp	8,620,266	10,254,357	-5.6%
Regents of the Univ. of CA/UCLA Outreach	4,362,512	3,522,142	7.4%
Childrens Hospital of Los Angeles	3,631,416	3,052,988	6.0%
Primex Clinical Labs	2,873,337	2,123,575	10.6%
Latara Enterprise (dba Foundation Laboratory)	2,519,603	3,300,925	-8.6%
Dignity Health	2,416,578	3,405,027	-10.8%
Rady Children's Hospital	2,262,335	NA	NA
Santa Clara Medical Center	2,141,774	2,147,865	-0.1%
H&M Molecular Diagnostics	1,944,840	NA	NA
Natera Inc.	1,914,701	NA	NA
City of Hope Helford	1,693,498	NA	NA
Loma Linda University	1,525,638	2,443,874	-14.5%
Hazel Hawkins Memorial Hospital	1,493,089	NA	NA
Biological Laboratory Inc.	1,440,884	2,561,679	-17.5%
Valley Childrens Hospital	1,381,544	NA	NA
Inspire Diagnostics LLC	1,361,991	NA	NA
UC Davis Medical Center	1,348,944	NA	NA
Grand Total, all Medi-Cal Labs	\$190,891,856	\$213,594,734	-3.7%

Source: California Dept. of Health Care Services



# Publicly-Traded Lab Revenue Fell 9.5% In 2022

On a combined basis, 24 publicly-traded labs reported a revenue decline of 9.5% to \$28.3 billion in full-year 2022 (after adjusting for acquisitions), according to financial reports collected by *Laboratory Economics*. A sharp drop-off in Covid-19 PCR testing was responsible for lower revenue for most labs in 2022.

Revenue growth was fastest at **ProPhase Labs** (Garden City, NY), up 55% to \$122.6 million. ProPhase operates CLIA-certified labs in Long Island, NY (25,000 sq. ft.) and northern New Jersey (4,000 sq. ft.). ProPhase's growth was driven by Covid-19 PCR, antigen and antibody testing. Overall test volume at ProPhase increased to 1 million tests (29% from the HRSA uninsured program) in 2022, up from 600,000 tests (58% from HRSA) in 2021. ProPhase is now in the process of expanding its menu beyond Covid-19 testing to offer traditional testing (hematology, chemistry, immunoassays, coagulation, STDs, urinalysis, etc.).

Revenue growth was also strong at **Veracyte** (South San Francisco, CA), up 35% to \$296.5 million; **Natera** (Austin, TX), up 31% to \$820.2 million; and **Dermtech** (La Jolla, CA), up 23% to \$14.5 million.

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

	Full-Year	Full-Year	Reported	Pro Forma
Company	2022	2021	Change	Change*
Quest Diagnostics (lab testing only)	9,609,000	\$10,494,000	-8.4%	-9.4%
LabCorp (lab testing only)	9,203,500	10,363,600	-11.2%	-12.3%
Sonic Healthcare USA <sup>1</sup>	1,527,900	1,623,698	-5.9%	-9.0%
Opko/Bio-Reference Labs	755,630	1,607,106	-53.0%	-53.0%
Enzo Clinical Labs (lab testing only) <sup>2</sup>	74,428	86,984	-14.4%	-14.4%
Total, 5 National/Clinical Labs	\$21,170,458	\$24,175,388	-12.4%	-13.5%
5 10 1	0.004.070	Å1 7/7 007	17.00/	7 ( 00)
Exact Sciences	2,084,279	\$1,767,087	17.9%	16.0%
Natera	820,222	625,486	31.1%	31.1%
Myriad Genetics	678,400	690,600	-1.8%	1.8%
Fulgent Genetics	618,968	992,584	-37.6%	-42.2%
Invitae Corp.	516,303	460,449	12.1%	12.1%
NeoGenomics	509,728	484,329	5.2%	5.0%
Guardant Health	449,538	373,653	20.3%	20.3%
CareDx	321,793	296,397	8.6%	8.6%
Veracyte	296,536	219,514	35.1%	35.1%
GeneDx (formerly Sema4)	234,694	212,195	10.6%	-13.4%
Konica Minolta/Ambry Genetics <sup>3</sup>	192,973	210,244	-8.2%	-8.2%
Castle Biosciences	137,039	94,085	45.7%	15.0%
ProPhase Labs	122,647	79,042	55.2%	55.2%
Exagen Inc.	45,563	48,299	-5.7%	-5.7%
Biodesix	38,212	54,506	-29.9%	-29.9%
Interpace Biosciences	31,838	33,117	-3.9%	-3.9%
Psychemedics	25,240	24,909	1.3%	1.3%
Dermtech	14,518	11,838	22.6%	22.6%
Aspira Women's Health	8,184	6,812	20.1%	20.1%
Total, 19 Specialty/Genetic Labs	7,146,675	6,685,146	6.9%	4.9%
Grand Total, All 24 Lab Companies	\$28,317,133	\$30,860,534	-8.2%	-9.5%

<sup>\*</sup>Pro forma change is estimated by Laboratory Economics after adjustments for acquisitions.

<sup>1</sup>Sonic Healthcare USA revenue is for the 12 months ended June 30, 2022 at constant exchange rate of 1 Australian Dollar equal to 0.725 U.S. Dollar. <sup>2</sup>Enzo's revenue is for lab services only for 12 months ended July 31, 2022. <sup>3</sup>Konica Minolta/Ambry Genetics revenue is for the 12 months ended March 31, 2022. Source: *Laboratory Economics* from company reports

# Lab Stocks Up 14% Year-to-Date In 2023

Twenty-four lab stocks have risen by an unweighted average of 14% year to date through April 14. In comparison, the S&P 500 Index is up 8% year to date. The top-performing lab stock thus far in 2023 is DermTech, up 134%. Enzo Biochem is up 78% and NeoGenomics is up 66%. Labcorp is down 3% and Quest Diagnostics is down 9%.

	Stock Price	Stock Price	2023 Price	Enterprise Value	Revenue for Trailing 12 mos.	Enterprise Value/
Company (ticker)	4/14/23	12/30/22	Change	(\$ millions)	(\$ millions)	Revenue
DermTech Inc. (DMTK)	\$4.15	\$1.77	134%	59	15	4.0
Enzo Biochem (ENZ)	2.54	1.43	78%	140	81	1.7
NeoGenomics (NEO)	15.32	9.24	66%	2,130	510	4.2
Myriad Genetics (MYGN)	22.27	14.51	53%	1,790	678	2.6
Exact Sciences (EXAS)	66.79	49.51	35%	13,730	2,084	6.6
Natera (NTRA)	51.40	40.17	28%	5,370	820	6.5
Opko Health (OPK)	1.55	1.25	24%	1,360	1,004	1.4
Sonic Healthcare (SHL.AX)*	36.29	29.97	21%	19,450	8,670	2.2
Interpace Biosciences (IDXG)	1.24	1.04	19%	63	32	2.0
GeneDx (formerly Sema4)	0.29	0.26	12%	184	235	0.8
Aspira Women's HIth (AWH)	0.36	0.33	9%	35	8	4.3
Psychemedics (PMD)	5.27	4.90	8%	29	25	1.1
Fulgent Genetics (FLGT)	30.83	29.78	4%	99	619	0.2
Exagen (XGN)	2.43	2.40	1%	15	46	0.3
Labcorp (LH)	229.35	235.48	-3%	26,260	14,877	1.8
Castle Biosciences (CSTL)	22.58	23.54	-4%	358	137	2.6
Veracyte (VCYT)	21.93	23.73	-8%	1,420	297	4.8
Quest Diagnostics (DGX)	142.34	156.44	-9%	20,440	9,883	2.1
Guardant Health (GH)	24.50	27.20	-10%	2,870	450	6.4
ProPhase Labs (PRPH)	8.16	9.63	-15%	130	123	1.1
Biodesix (BDSX)	1.80	2.30	-22%	129	38	3.4
CareDx (CDNA)	8.88	11.41	-22%	223	322	0.7
Invitae (NVTA)	1.37	1.86	-26%	1,540	516	3.0
Biocept (BIOC)	0.35	0.53	-34%	0.4	50	0.0
Totals & Averages			14%	\$97,822	\$41,519	2.4

<sup>\*</sup>Sonic Healthcare's figures are in Australian dollars

Source: Laboratory Economics from Seeking Alpha.com

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# Top 25 PCR-Based Microbiology Testing Labs

Vikor Scientific (Charleston, SC) is the top PCR-based microbiology testing lab in the United States in terms of Medicare Part B Carrier allowed test volume for 20 microbiology test codes (see table). Vikor had allowed volume of 644,443 PCR-based microbiology tests for Medicare patients in 2020 (the latest year of available data). Other big PCR-based microbiology testing labs include Gamma Healthcare (Poplar Bluff, MO), Corona Pathology (Burbank, CA) and Biodxx (Mechanicsburg, PA).

Top 25 PCR-Based Microbiology Testing Labs\*

Laboratory	Location	Total Medicare Part B Tests for 2020	Total Medicare Part B Allowed Amount for 2020
Vikor Scientific	Charleston, SC	644,443	\$25,488,499
Gamma Healthcare	Poplar Bluff, MO	520,544	\$18,206,031
Corona Pathology	Burbank, CA	474,849	\$18,983,625
Biodxx, Inc.	Mechanicsburg, PA	392,512	\$15,774,954
Cap Diagnostics (dba Pathnostics)	Irvine, CA	384,735	\$14,635,536
Magnolia Diagnostics	Dallas, TX	381,600	\$21,745,194
Ispm Labs	Atlanta, GA	355,452	\$15,027,021
Medarbor	Bristol, PA	304,051	\$11,912,469
Beach Tox	Torrance, CA	233,014	\$9,237,497
MD Spine Solutions (dba MD Labs)	Reno, NV	209,930	\$7,299,495
Patients Choice Laboratories of Indiana	Indianapolis, IN	204,728	\$7,225,547
Labcorp	Burlington, NC	173,229	\$6,817,494
Silverpath, Inc.	Blue Bell, PA	167,461	\$7,359,966
Provista Health	Scottsdale, AZ	160,309	\$6,201,301
Genetic Technological Innovations	Scottsdale, AZ	145,294	\$5,808,920
Matias Clinical Laboratory Inc	Baldwin Park, CA	118,406	\$6,038,353
American Institute of Toxicology	Denton, TX	117,023	\$4,145,128
Cell Diagnostics Inc	Pasadena, CA	112,836	\$4,201,454
Scott Acker, MD/Bako Diagnostics	Alpharetta, GA	111,820	\$3,890,743
Proteus Molecular and Clinical Lab	Homewood, AL	109,286	\$4,000,714
Mako Medical Laboratories	Raleigh, NC	95,138	\$3,335,413
Eurofins Diatherix Laboratories	Huntsville, AL	93,945	\$2,814,171
Southwest Regional PCR	Lubbock, TX	88,640	\$3,753,302
Ocean Marketing Corp.	San Pedro, CA	86,435	\$3,502,001
Physicians Group Laboratories	Houma, LA	86,282	\$3,357,861

<sup>\*</sup>Includes CPT 87798, 87150, 87481, 87801, 87640, 87653, 87799, 87500, 87651, 87641, 87491, 87591, 87581, 87486, 87631, 87661, 87529, 87502, 87541, 87634

Source: Laboratory Economics from CMS