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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

New Law Delays Medicare Cuts To Both CLFS And Pathologists

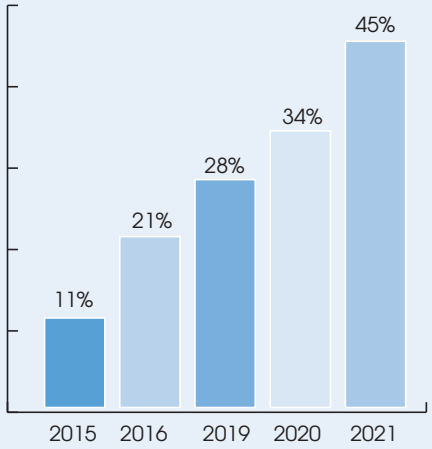
On December 10, President Biden signed into law legislation that delays a wide range of Medicare rate cuts that would have hurt both clinical labs and pathologists in 2022. The Protecting Medicare and American Farmers from Sequester Act (S. 610) freezes the Medicare Clinical Laboratory Fee Schedule (CLFS) for another year in 2022. The new law also provides a one-year 3% increase for the Medicare Physician Fee Schedule (MPFS), which will help offset most of the average 4% cut that pathologists and pathology labs were facing next year.
Full details on page 3.

Staffing Shortages Are Fastest Rising Challenge

A *Laboratory Economics* survey in December 2021 asked lab executives and pathologists what they saw as the biggest challenges they would face over the next five years. The top answer among the total 134 survey respondents was declining reimbursement (cited by 83%). That's not shocking—declining reimbursement has been the top concern since *LE* conducted its very first survey back in 2007.

The outlier in this year's survey was the jump in survey respondents citing "technical staff shortages" as one of their biggest challenges—up to 45% versus 34% last year. *Continued on page 5.*

Technical Staff Shortages Are A Big Challenge



Source: *Laboratory Economics Surveys* (December 2021, October 2020, July 2019, August 2016 and July 2015—no comparable *LE* surveys were conducted in 2017 and 2018)

Clarapath Aims To Automate Microtomy

Clarapath Inc. (Hawthorne, NY) is seeking to automate microtomy--the only stage of tissue slide preparation that has not yet been automated in histology labs. Manual tissue block cutting and transfer to glass slides remains a bottleneck that limits throughput, notes Clarapath CEO Eric Feinstein. He says the company's automated tissue sectioning device, SectionStar, will be marketed for research-use-only to pharmaceutical companies, veterinary labs and toxicologists starting early next year. Clarapath also plans to submit an application for SectionStar to the FDA for clearance in the clinical diagnostics market. *Continued on page 2.*

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Clarapath Aims To Automate Microtomy (*cont'd from page 1*)

Clarapath was founded in 2014 as a spin-off of Dr. Partha Mitra's research on high-throughput neuroanatomy at the research institute Cold Spring Harbor Laboratory (Long Island, NY). Mitra, who has a PhD in theoretical physics from Harvard University, is the Chairman of Clarapath.

Partha Mitra, PhD

The need for automated microtomy was highlighted during Mitra's research into whole-brain digital neuroanatomy, which requires digitized whole-brain anatomical datasets. However, prior to producing digitized slide images of the brain, Mitra had to first make hundreds of thousands of tissue sample slides using the tape-transfer method for high-quality microtomy.

The tape-transfer method was originally developed to facilitate the transference of frozen tissue sections to glass slides for clinical diagnostics in anatomic pathology. Historically, tape-transfer has not been used for routine paraffin wax tissue processing.

Mitra had the idea to use the tape-transfer method as a foundation to develop a fully automated microtomy system. SectionStar automates tissue cutting and then transfers each section to tape. The tape acts like a conveyor belt to directly deposit each section to a glass slide. It eliminates the inconsistencies of manual section cutting as well as quality control problems that can occur when using the traditional water bath method of transference to glass slides, according to Feinstein.

Eric Feinstein

Feinstein says SectionStar is capable of processing 72 tissue blocks into 150-250 glass slides every three hours. "It gives the histotech three hours of 'walk-away' time that can be spent working on other things in the lab."

The system, which fits on a desktop, was developed in cooperation with Northwell Health (New Hyde Park, NY), which is also an investor in the company. Beta-testing occurred at Northwell with an earlier prototype of SectionStar, which helped guide further design. Further beta-testing at Northwell is expected, according to James Crawford, MD, PhD, Senior Vice President of Laboratory Services at Northwell. Crawford is also a board member at Clarapath and has served Clarapath's Technical Advisory Group since the inception of the company.

In addition to increased productivity, Crawford says that the SectionStar direct-transfer process eliminates many of the chronic problems with water bath histology, namely tears, folds, and the potential for floaters. In addition, SectionStar has a ground-up re-engineered microtome that essentially eliminates "chatter." "The human eye can see through these histologic artifacts for the purposes of interpretation and diagnosis. However, moving into a digital pathology world, with AI-assisted interpretation, the quality control for the input images has to be of the highest quality," notes Crawford.

Feinstein anticipates that SectionStar will sell for roughly $200,000 to $300,000 plus variable costs of $15,000 to $20,000 per year depending on volume. The target market is medium to large size histology labs. He expects these labs to get a return on their investment from SectionStar within 12-18 months from higher throughput/increased histotech productivity.

In addition, Clarapath runs a CLIA-certified lab in Manhattan that offers a range of histology services.

Clarapath recently raised $31.5 million from a series B funding, bringing its total raised to date to more than $39 million. In addition to Northwell Health, Clarapath's investors include Epiphron Capital, P5 Health Ventures, and East Post Road Ventures (the investment arm of White Plains Hospital).

New Law Delays Medicare Cuts (*cont'd from page 1*)
Over 100 national associations and dozens of state advocacy associations had lobbied for the legislative relief, including the College of American Pathologists, American Clinical Laboratory Association, American Medical Association, California Medical Association, etc.

The Protecting Medicare and American Farmers from Sequester Cuts Act was approved by the U.S. House of Representatives (222 Yeas/212 Nays) on December 7 and passed the U.S. Senate (59 Yeas/35 Nays/6 No votes) on December 9.

The new law provides relief for every big item that clinical labs and pathologists had been lobbying for, including:

- **Medicare CLFS Rate Freeze:** Scheduled rate cuts of up to 15% for some 600 lab tests on the Medicare CLFS have been delayed for another year until January 1, 2023. This follows a similar freeze in Medicare CLFS rates that took place in 2021.
- **PAMA Reporting Delay:** The second round of private-payer payment data reporting by independent labs, hospital outreach labs and large physician-office labs has been delayed by one year. The PAMA payment reporting period is now scheduled for January 1, 2023 to March 31, 2023. CMS will use this data to calculate new CLFS rates for 2024-2026.
- **Physician Fee Schedule Relief:** Pathologists and pathology labs will benefit from a one-year rate increase of 3% for services paid through the Medicare PFS. This bump will largely offset the scheduled 3.75% reduction to the conversion factor triggered by statutory budget neutrality requirements. For example, the Medicare PFS global rate for CPT 88305 (Level 4-Surgical pathology) will now be raised by approximately 1% in 2022 versus the previous expectation of a 2% cut.
- **Delay of 2% Medicare Sequestration Cut:** The new law includes a three-month extension of the 2% sequester relief applied to all Medicare payments (both CLFS and PFS) through March 31, 2022, followed by 3 months of 1% sequester relief through June 30, 2022. Sequester relief would then end on June 30, 2022.
- **Prevents Medicare PAYGO Cut:** Medicare Pay-As-You-Go cuts of 4% that had been scheduled to go into effect on January 1, 2022 have been suspended. Like sequestration, PAYGO cuts go into effect when Congress fails to balance the budget. However, statutory PAYGO cuts have never occurred since the law was enacted in 1990.

The one-year delay to Medicare CLFS rate cuts and private-payer data reporting buys time to develop a longer-term legislative fix to PAMA, according to Mark Birenbaum, PhD, Executive Director of the National Independent Lab Association (NILA), which represents small independent labs. "Otherwise the lab industry will be faced with the same situation again in 2023," he notes. In particular, NILA and ACLA want CMS to move to a statistical sampling model that ensures that private-payer rates from all segments of the lab market (independent, hospital and physician-office lab) are fairly represented when Medicare CLFS rates are formulated.

Separately, the Medicare Trustees' Report for 2021 shows the Part A trust fund, which provides inpatient/hospital coverage, will be insolvent by 2026 and Medicare spending will rise rapidly as a share of GDP over the next quarter-century. The overall Medicare program (Parts A, B, C and D) is currently underfunded by a whopping $55 trillion—an amount equal to $379,000 per American taxpayer! (See Medicare Trustees Report for 2021, pages 221-222.)

Court Finds EKRA Permits Commission Payments To Lab Sales Rep

A lawsuit between a toxicology laboratory and a former sales manager has resulted in an unanticipated interpretation of the Eliminating Kickbacks in Recovery Act (EKRA).

The EKRA Law passed as part of the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Communities Act in October 2018. EKRA was intended to target patient brokers who improperly profit from patients trying to recover from addiction. But the law also included provisions that seemingly outlawed all CLIA labs from paying commissions to sales reps based on the number of patients referred, test volume, or the amount billed to a commercial health plan.

Healthcare lawyers interpreted EKRA as prohibiting all labs from paying volume-based sales commissions to either W2 employees or independent 1099 contractors (see *LE*, July 2021, May 2019, April 2019 and December 2018). However, a U.S. District Court in Hawaii has decided that's not the case.

The matter involves a lawsuit between S&G Labs Hawaii (Kailua Kona) and former sales manager Darren Graves (Civ. No. 19-00310, 2021 WL 4847430). Graves became a sales manager at S&G in March 2017 under an employment contract that was scheduled to end in March 2023. His compensation included a base annual salary of $50,000 plus a percentage of the monthly net profits generated by his client accounts and by the client accounts handled by the employees he managed.

S&G Labs is a toxicology lab founded by its President Lynn Welch Puana, MD, a practicing pain physician, in 2015. In early 2019, S&G's law firm advised Dr. Puana that she could face criminal penalties under EKRA if her lab continued to pay volume-based sales commissions to its sales team. As a result, Dr. Puana began to negotiate a new salary-based compensation agreement with Graves.

Unable to reach an agreement, S&G terminated Graves' employment contract. Litigation followed. Graves claimed that S&G had breached its employment contract and he was due unpaid wages. S&G replied that those payments would have violated EKRA, and that the statute made the contract provisions for commission-based payments illegal and unenforceable. S&G requested the court to award it summary judgment on this basis.

However, the court determined that S&G payments to Graves would not violate the EKRA prohibition against paying or offering remuneration "(A) to induce a referral of an individual to a … laboratory; or (B) in exchange for the individual using the services of that …laboratory…." 18 U.S.C. 220(a)(2)(A),(B).

Robert Mazer

The court recognized that "individual," as referenced in section A of the EKRA prohibition (above), referred to the patient undergoing testing. However, according to the court, because sales efforts were directed towards physicians and other lab clients, the sales manager was not paid to induce referrals of individuals to the lab as EKRA prohibited, notes Robert Mazer, Senior Counsel at Baker Donelson (Baltimore, MD).

The court concluded that the employment agreement did not violate EKRA. Therefore, when S&G refused to pay Graves amounts that were due under the agreement, it breached the parties' contract and became liable for damages.

"I don't think this decision is a game changer that says that labs can make commission-based compensation to their sales reps ," says Mazer. "EKRA specifically authorizes the Attorney General, working in consultation with the Secretary of Health and Human Services, to publish regulations clarifying EKRA exceptions. Hopefully any such clarifications would also address whether commission-based payments violate the statute's basic prohibitions. But it's been three years since the EKRA law was enacted and we're still waiting for additional guidance."

LE Survey: Staffing Shortages Are Fastest Rising Challenge (*cont'd from page 1*)

The *LE* survey also showed that "pathologist shortages" are also a growing concern. Twenty-percent of survey respondents cited pathologist shortages as one of the biggest challenges facing labs and pathology groups, up from only 3% in last year's survey.

"The pandemic has nudged some older pathologists to retire early," according to a hospital lab executive from Illinois.

"Technical staffing shortages are driving up costs and reducing quality," said a hospital-based pathologist from Texas.

Health Insurance Payer Issues

"Declining reimbursement" has consistently been the top challenge. Other health insurance related challenges include "exclusion from managed care contracts" (33%) and "prior authorization test order requirements" (21%).

"Declining insurance payments and increased denials are a problem. And patients think that because they have insurance, they are covered 100% and don't pay their balance," lamented a pathologist from Colorado.

"Payers implementing pre- and post-payment reviews for certain pathology codes are slowing down the entire process and increasing denials," noted an independent lab executive from Nevada.

"Insurance companies control testing and what is considered 'covered.' All services outside of routine are being applied to deductibles for payment from patients," according to an independent lab executive from Texas.

The Pandemic

Only 12% of surveyed labs and pathologists saw the current Covid-19 pandemic as one of the biggest challenges for the next five years, down from 27% in last year's survey.

What are the biggest challenges that labs and pathology groups will face over the next 5 years?*

	2021	2020	2019	2016	2015
Declining reimbursement	83%	81%	82%	89%	74%
Technical staff shortages	45%	34%	28%	21%	11%
Exclusion from managed care contracts	33%	44%	47%	45%	41%
Competition from large commercial labs	30%	28%	42%	36%	36%
Specialty physician groups insourcing pathology	26%	16%	25%	36%	30%
Prior authorization test order requirements	21%	38%	28%	13%	6%
Pathologist shortages	20%	3%	11%	6%	2%
The Covid-19 pandemic	12%	27%	NA	NA	NA
Difficulty/expense of adding new molecular tests	9%	6%	14%	12%	14%
Increased expenses for information technology	9%	14%	14%	13%	17%

*Survey participants were asked to pick their top three challenges

Source: *Laboratory Economics Surveys* (December 2021, October 2020, July 2019, August 2016 and July 2015—no comparable *LE* surveys were conducted in 2017 and 2018)

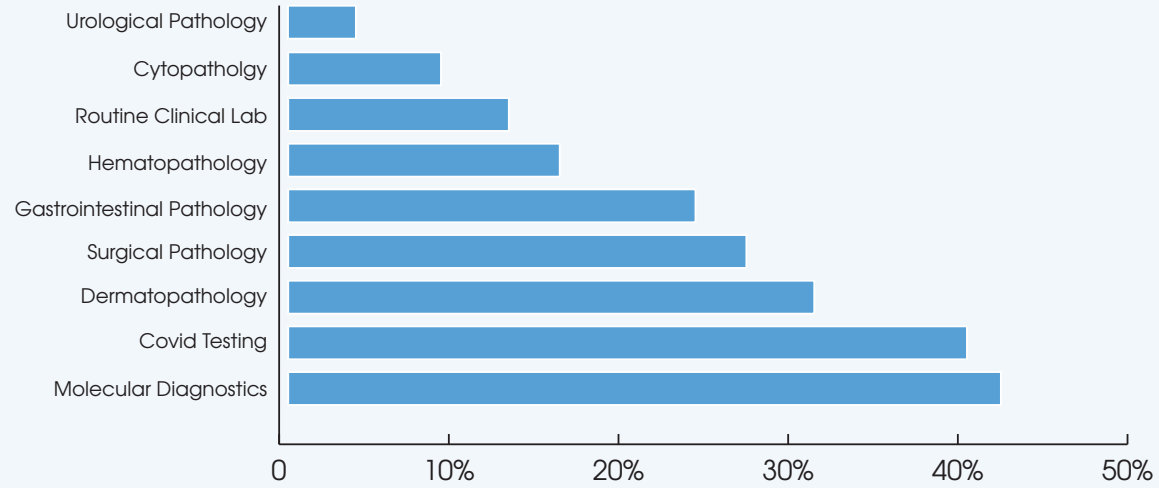
Survey Demographics: The survey was e-mailed to approximately 6,000 pathology groups, independent labs and hospitals in early December 2021. A total of 134 surveys were judged usable, yielding a response rate of 2.2%. Among the respondents, 59 were from local or regional independent pathology groups and labs, 26 from hospital-based pathology groups or labs, 13 from national pathology or lab companies, 13 from hospital-based outreach labs, 11 from academic medical center-based pathology groups, seven from in-office pathology labs, and five from "other" labs.

Which Subspecialty is Growing Fastest?

Forty-two percent of survey respondents said they were seeing their fastest growth in molecular test volumes, according to *LE's Anatomic Pathology & Clinical Lab Trends Survey* in December 2021. The second fastest area of growth was Covid-19 testing (cited by 40%), followed by dermatopathology (31%). The slowest areas of growth were urologic pathology (4%) and cytopathology (9%).

"The movement toward true personalized medicine in diagnosis and in treatment continues to grow," according to a genetic testing lab executive from Florida.

In which subspecialties is your pathology group/lab seeing its fastest growth?*

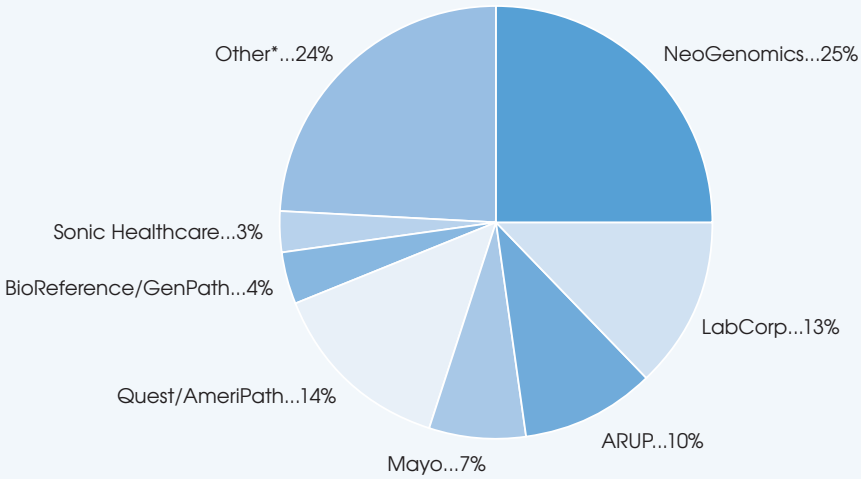


*Survey participants were asked to pick their top 3
Source: *LE's* Anatomic Pathology & Clinical Lab Trends Survey, December 2021

Reference Lab Market Share for Cancer Testing

NeoGenomics is the primary reference lab for cancer testing for 25% of surveyed pathology groups and labs. Quest Diagnostics, including its AmeriPath division, had a 14% share, followed by Labcorp, including its Integrated Oncology division, with a 13% share. ARUP Laboratories has a 10%, Mayo Clinic Labs (7%), BioReference Labs/GenPath (4%) and Sonic Healthcare USA (3%).

Who is you Primary Reference Laboratory for Cancer Testing?

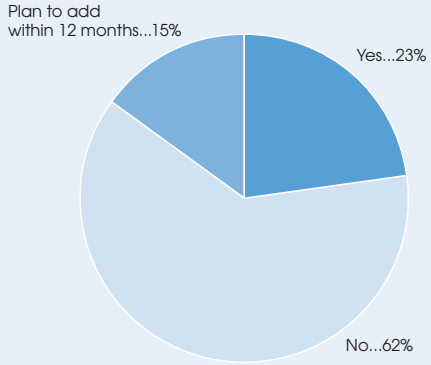


*Other labs cited included Caris Life Sciences, Foundation Medicine, Genetics Institute of America, PathGroup, UCSF Dermatopathology, University of Alabama and Yale University
Source: *LE's* Anatomic Pathology & Clinical Lab Trends Survey, December 2021

Adoption Trends in Digital Pathology

Twenty-three percent of pathology groups and labs in the United States currently have digital imaging systems in place for analyzing patient specimens, and another 15% said they plan to add a system within 12 months, according to *LE's Anatomic Pathology & Clinical Lab Trends Survey* in December 2021.

Does your pathology group/laboratory use digital pathology to analyze patient slides?



Source: *LE's* Anatomic Pathology & Clinical Lab Trends Survey, December 2021

The biggest clinical market for digital pathology is currently in quantitative immunohistochemistry for HER2 (cited by 75% of digital pathology users). Other uses of digital pathology include education and/or training (69%), ER/PR scoring (50%), and second opinions and/or consultations (50%). Less than half of digital pathology users have employed it for primary clinical diagnosis in surgical pathology (44%), although this figure has substantially risen from previous surveys.

What do you use digital pathology for?*

	2021	2019	2016
HER2 scoring	75%	57%	56%
Education and/or training	69%	34%	54%
ER/PR scoring	50%	43%	35%
Second opinions and/or consultations	50%	40%	50%
Primary clinical diagnosis	44%	6%	20%
Archiving specimens	31%	14%	19%
Contract research for clinical trials	13%	3%	13%
Photography of autopsies	13%	5%	0%
Remote frozen section interpretations	13%	0%	0%

*Survey respondents were able to select multiple answers

Source: *LE's Anatomic Pathology & Clinical Lab Trends Surveys*, December 2021, July 2019 & Sept. 2016

The percentage of digital pathology users has remained fairly stable since *LE's* first survey in 2009.

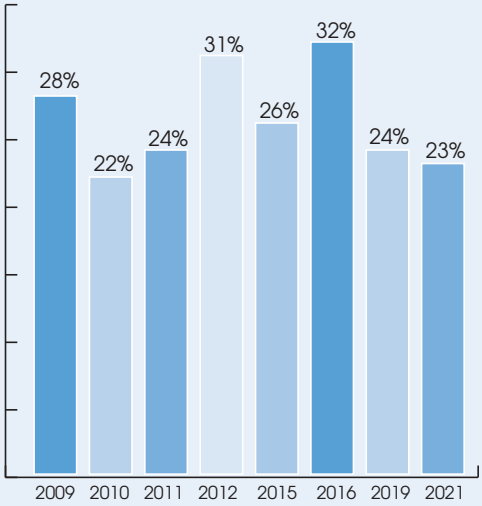
The most common reasons cited for not using digital pathology have consistently been "too expensive" and "traditional pathology/microscope works fine." In short, digital pathology is an added expense that is not reimbursed.

"The move to digital pathology is difficult to get approved in a hospital setting with limited budgets," according to a hospital lab director from California.

However, adoption might be on the verge of accelerating, as new artificial intelligence (AI) systems are introduced. AI-based decision-support tools are proving to boost pathologist productivity and accuracy. AI requires digitization and thus may drive digital pathology adoption rates.

"Digital pathology combined with AI has the potential to disrupt current business models," noted an independent lab director from New York.

Percentage of Labs that Report Using Digital Pathology



Source: *LE's* Anatomic Pathology & Clinical Lab Trends Surveys: 2009-2012, 2015, 2016, 2019 and 2021

MD Labs Regains Medicare Billing Privileges

Nevada-based MD Spine Solutions (doing business as MD Labs) regained its Medicare billing privileges effective November 3, according to President Matthew Rutledge.

CMS had suspended Medicare payments to MD Labs on April 13, 2021. The suspension was related to U.S. Department of Justice charges that MD Labs had billed Medicare for medically unnecessary urine drug tests (UDTs) between 2015 and 2019. MD Labs recently settled these allegations by agreeing to pay up to $16 million (see *LE*, November 2021).

"Getting back in good standing with Medicare was an important factor that drove us to settle. We hold ourselves to the highest ethical standards in meeting our commitment to doctors and patients, and we are pleased to have resolved this matter and put it behind us," according to Rutledge.

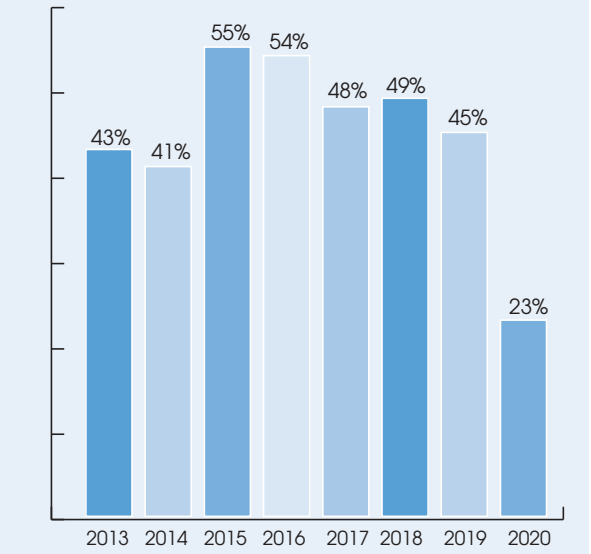
Genetic Test Claims Denials Plunged Last Year. Why?

Only 23% of genetic test claims were denied by Medicare Part B contractors in 2020, according to an exclusive analysis of the latest available Part B carrier data by *Laboratory Economics*. This is a substantial improvement from the historical denial rate for genetic test claims, which had averaged between 41% to 55% between 2013 and 2019.

The cause of the reduced denial rates is not entirely clear. However, the U.S. Department of Justice's crackdown on genetic testing fraud, dubbed "Operation Double Helix," did put several big laboratory companies out of business in late 2019 and early 2020. These labs were responsible for a high volume of claims denials and their removal has lowered the overall average denial rate.

Operation Double Helix may have also "scared straight" many smaller genetic testing labs into more conservative Medicare billing practices, notes *Laboratory Economics*.

Medicare Part B Claims Denial Rates for Genetic Tests



Source: Medicare Part B aggregate denied claims vs. submitted claims for CPT codes 81105-81599 and G0452, 0037U and 0097U for 2013-2020

Genetic Labs That Went Out of Business

LabSolutions (Atlanta, GA) was the biggest genetic testing lab charged by the DOJ for submitting false claims to Medicare. LabSolutions was formed in 2013 and initially focused on toxicology testing, then switched mostly to genetic testing in 2016.

LabSolutions owner Minal Patel was indicted in September 2019 on charges of healthcare fraud (see *LE*, October 2019). According to the DOJ, LabSolutions solicited medically unnecessary genetic tests from Medicare beneficiaries through telemarketing and health fairs. The tests were then approved by telemedicine doctors who allegedly did not engage in treatment of the beneficiaries, and often did not even speak with the patients for whom they ordered tests.

LabSolutions received more than $170 million in Medicare payments between 2016 and 2019, but went out of business within a few months after the DOJ indictment.

Other labs charged by the DOJ in late 2019 for similar alleged genetic testing scams were **Acadian Diagnostic Laboratories** (Baton Rouge, LA), **CLIO Laboratories** (Lawrenceville, GA), **Performance Labs** (Oklahoma City, OK) and **Lazarus Services** (New Orleans, LA).

Acadian has changed its name to Pharos Health and is now marketing respiratory virus panels and Covid-19 testing. Pharos Health is currently hiring sales reps throughout the country.

Meanwhile, CLIO Laboratories, Performance Labs and Lazarus Services have each gone out of business.

All the aforementioned labs (LabSolutions, Acadian, CLIO, etc.) had billed Medicare for some of the most controversial genetic testing codes with high denial rates, including CPT 81479 (unlisted molecular pathology procedure).

Pre-Authorization Requirements

In addition, payers have established pre-auth requirements that have led to many orders being abandoned for patients by the ordering physicians who have difficulty navigating through the pre-auth process, according to Lale White, Executive Chairman and CEO at *XIFIN* Inc. (San Diego, CA). In particular, pharmacogenetics, which are used to predict individual response to a variety of prescription drugs, often have pre-auth requirements and high denial rates. White notes that some labs have stopped offering those tests to Medicare patients or have made them cash pay services. As a result, the volume of pharmacogenetic test claims going to Medicare has been decreasing. For example, two of the highest volume pharmacogenetic test codes CPT 81225 (CYP2C19 genotype) and CPT 81226 (CYP2D6 genotype), each saw Medicare Part B carrier volume declines of more than 60% in 2020.

Medicare Part B Carrier Claims Denial Rates for Top 20 Genetic Tests for 2020

CPT	Short Description	Submitted Claims	Denied Claims	Percent Denied
81528	Cologuard colorectal cancer screening	428,469	15,205	3.5%
81479	Unlisted molecular pathology procedure	274,855	136,113	49.5%
81404	Molecular pathology procedure, Level 5	172,108	25,070	14.6%
G0452	Molecular pathology interpretation	157,833	20,713	13.1%
81405	Molecular pathology procedure, Level 6	119,783	14,959	12.5%
81406	Molecular pathology procedure, Level 7	119,031	16,179	13.6%
81408	Molecular pathology procedure, Level 9	118,765	14,845	12.5%
81401	Molecular pathology procedure, Level 2	67,138	15,192	22.6%
81162	BRCA1, BRCA2 full seq analysis & full dup/del analysis	62,437	15,678	25.1%
81403	Molecular pathology procedure, Level 4	56,212	8,196	14.6%
81407	Molecular pathology procedure, Level 8	47,771	6,415	13.4%
81291	MTHFR gene analysis	35,084	26,780	76.3%
81241	Factor V gene analysis	32,974	27,671	83.9%
81490	Vectra DA rheumatoid arthritis test	31,440	1,707	5.4%
81240	Factor II gene analysis	29,190	24,446	83.7%
0097U	BioFire FilmArray Gastrointestinal Panel	26,431	2,681	10.1%
81270	JAK2 gene analysis	25,660	6,938	27.0%
81225	CYP2C19 genotype	25,302	17,075	67.5%
81226	CYP2D6 genotype	23,739	14,480	61.0%
0037U	FoundationOne CDx	23,518	1,377	5.9%
	Total for top 20 Part B genetic tests	1,877,740	411,720	21.9%
	Total for all Part B genetic tests	**2,567,515**	**587,961**	**22.9%**

Source: Medicare Part B national carrier data for CPT codes 81105-81599 and G0452, 0037U and 0097U for 2020

Non-Covid Test Volumes Plunged Last year

The volume of laboratory and pathology test services (excluding Covid testing) provided to Medicare Part B patients fell by 11% in 2020, according to new data released by CMS. Allowed test volumes for toxicology were hit the hardest (-23%), followed by Pap/HPV testing for cervical cancer (-18%) and genetic testing (-15%).

Pandemic lockdowns and fear kept many Medicare patients away from doctor's offices and limited lab test ordering in 2020.

Medicare Part B Carrier Allowed Test Volume*

Category	Allowed Volume 2020	Allowed Volume 2019	% Change
Clinical Lab (excluding Covid)	261,429,432	292,953,121	-11%
Anatomic Pathology	34,958,526	40,456,223	-14%
Covid Testing	11,729,088	0	NA
Toxicology	7,343,735	9,538,845	-23%
Genetic Testing	1,979,554	2,339,326	-15%
Pap/HPV	869,776	1,065,419	-18%
Total (excl. Covid) Part B Allowed Volume	306,581,023	346,352,935	-11%
Grand Total Part B Allowed Volume	318,310,111	346,352,935	-8%

*Note: Includes all Medicare Part B Carrier allowed test volume for 2020 (predominantly independent labs and POLs). Excludes Part B utilization data for institutional services (hospital outpatient departments, home health agencies, comprehensive outpatient rehab facilities, end-stage renal disease facilities, and rural health clinics) which are processed by Medicare Part A fiscal intermediaries and are not included in this data.

Source: *Laboratory Economics* from CMS

Meanwhile, an analysis of the highest-volume Medicare Part B Carrier tests shows that volume for 23 out of the top 25 tests declined in 2020 (see table, page 11).

Prothrombin Time

The sharpest volume decline occurred for prothrombin time (CPT 85610), which is used to evaluate blood clotting. Prothrombin time testing is commonly used to see how well warfarin is working. Warfarin is a blood-thinning medicine that's used to treat and prevent dangerous blood clots. The Medicare Part B Carrier allowed volume of prothrombin time tests fell by 25% to 6.3 million in 2020.

Surgical Pathology

Medicare Part B Carrier allowed volume for the most commonly performed surgical pathology procedure (CPT 88305, Level IV - surgical pathology) fell by 16% to 16.8 million in 2020.

Molecular Diagnostic Infectious Disease Testing

The only test to record increased volume was CPT 87798 (Infectious agent detection by DNA or RNA, each organism). This test was frequently ordered to rule out Covid-19 in patients presenting with upper respiratory virus symptoms, especially during the first half of 2020 when testing capacity for Covid-19 was limited. Medicare Part B Carrier allowed volume for CPT 87798 increased by 100% to 5.2 million tests in 2020.

Covid-19 Testing

High-throughput Covid-19 amplified probe (U0003) test volume paid by Medicare Part B Carriers totaled 7.2 million allowed tests in 2020. A total of 8.6 million tests for U0003 were submitted with 1.4 million denied tests for a denial rate of 16%.

Medicare Part B Carrier Allowed Test Volume* for Top 25 Tests

CPT Code	Description	Allowed Volume 2020	Allowed Volume 2019	% Chg
80053	Comprehensive metabolic panel	26,183,793	29,134,190	-10%
85025	Complete blood count (CBC)	26,165,595	29,390,003	-11%
80061	Lipid panel	17,034,922	19,125,606	-11%
88305	Level IV - surgical pathology	16,846,931	20,161,202	-16%
84443	Thyroid stimulating hormone (TSH)	13,433,766	15,101,077	-11%
83036	Hemoglobin; glycosylated (A1C)	13,268,840	15,189,337	-13%
U0003	Covid-19 amplified probe (high through-put)	7,229,296	0	NA
85610	Prothrombin time	6,318,126	8,396,009	-25%
81001	Urinalysis, automated with microscopy	6,125,616	7,117,920	-14%
80048	Basic metabolic panel	5,820,837	7,060,334	-18%
82306	Vitamin D	5,802,244	6,351,398	-9%
81003	Urinalysis, automated without microscopy	5,361,871	6,439,941	-17%
87798	Infectious agent detection by DNA or RNA, each organism	5,173,208	2,591,912	100%
84439	Free thyroxine (free T4)	4,844,636	5,338,742	-9%
82570	Creatinine	4,292,140	4,713,748	-9%
87086	Urine Culture	4,250,766	5,114,815	-17%
82607	Vitamin B12	3,731,441	4,134,326	-10%
82043	Albumin	3,415,813	3,775,233	-10%
85027	Complete blood count (CBC), automated	3,181,064	3,601,377	-12%
88341	Immunohistochemistry	3,134,774	3,270,356	-4%
83735	Magnesium	3,126,033	3,344,763	-7%
84153	Total PSA	3,053,965	3,324,501	-8%
83540	Iron	2,820,841	3,089,136	-9%
82728	Ferritin	2,751,700	2,967,762	-7%
84550	Uric acid, blood	2,748,001	3,101,122	-11%
Total	Top 24 test codes (excluding Covid)	188,886,923	211,834,809	-11%
Total	Top 25 test codes	196,116,219	211,834,809	-7%

*Note: Includes all Medicare Part B Carrier allowed test volume for 2020 (predominantly independent labs and POLs). Excludes Part B utilization data for institutional services (hospital outpatient departments, home health agencies, comprehensive outpatient rehab facilities, end-stage renal disease facilities, and rural health clinics) which are processed by Medicare Part A fiscal intermediaries and are not included in this data.

Source: *Laboratory Economics* from CMS

Quest Diagnostics Buys Labtech Diagnostics

Quest Diagnostics has acquired substantially all assets of Labtech Diagnostics (Anderson, SC), an independent clinical lab serving South and North Carolina, Georgia and Florida. Labtech has 200 employees and estimated annual revenue of $30-$50 million. Quest plans to maintain Labtech's CLIA-certified lab and offices in South Carolina.

Lab Stocks Down 6% Year To Date

Twenty-three lab stocks fell by an unweighted average of 6% year to date through December 13. In comparison, the S&P 500 Index is up 27% thus far in 2021. The top-performing lab stocks so far have been Interpace Biosciences, up 134%; Fulgent Genetics, up 67%; and Psychemedics, up 45%. Labcorp is up 44%, Quest Diagnostics, +37%, and Sonic Healthcare, +38%.

Company (ticker)	Stock Price 12/13/21	Stock Price 12/31/20	2021 Price Change	Enterprise Value ($ mill)	Enterprise Value/ Revenue	Enterprise Value/ EBITDA
Labcorp (LH)	$292.44	$203.55	44%	$31,970	1.9	6.9
Quest Diagnostics (DGX)	163.26	119.17	37%	23,300	2.1	6.8
Sonic Healthcare (SHL.AX)*	44.25	32.15	38%	23,260	2.7	9.1
Exact Sciences (EXAS)	78.02	132.49	-41%	14,830	8.4	NA
Guardant Health (GH)	94.16	128.88	-27%	9,410	27.4	NA
Natera (NTRA)	90.05	99.52	-10%	7,820	13.8	NA
Invitae (NVTA)	16.26	41.81	-61%	4,100	9.4	NA
NeoGenomics (NEO)	31.70	53.84	-41%	4,030	8.3	45.6
Opko Health (OPK)	3.89	3.95	-2%	2,730	1.5	13.9
Veracyte (VCYT)	40.42	48.94	-17%	2,640	14.1	NA
Fulgent Genetics (FLGT)	86.95	52.10	67%	2,030	2.0	2.7
CareDx (CDNA)	42.07	72.45	-42%	1,930	7.0	NA
Myriad Genetics (MYGN)	25.52	19.77	29%	1,710	3.1	NA
Castle Biosciences (CSTL)	40.42	67.15	-40%	865	10.0	NA
Progenity (PROG)	2.52	5.31	-53%	506	6.7	NA
DermTech Inc. (DMTK)	16.68	32.44	-49%	274	25.4	NA
Aspira Women's Hlth (AWH)	1.71	6.71	-75%	156	24.3	NA
Enzo Biochem (ENZ)	3.54	2.52	40%	154	1.3	19.0
Biodesix (BDSX)	4.71	20.16	-77%	115	1.6	NA
Exagen (XGN)	9.29	13.20	-30%	95	2.0	NA
Interpace Biosciences (IDXG)	7.35	3.14	134%	89	2.2	NA
Biocept (BIOC)	3.86	4.44	-13%	52	0.8	8.8
Psychemedics (PMD)	7.4	5.09	45%	46	1.9	11.9
Unweighted Averages			-6%	$132,112	7.7	13.9

*Sonic Healthcare's figures are in Australian dollars

Source: *Laboratory Economics* from company reports and Capital IQ

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