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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

FDA Won't Extend Comment Period on LDT Regs

The FDA has announced that its standard 60-day comment period for its proposed regulation of laboratory-developed test (LDTs) will not be extended past December 4. Several trade groups, including CAP and ACLA, had requested to stretch the comment period to 120 days. An extension would have potentially delayed implementation of the rule while giving Congress more time to pass LDT reform legislation. The FDA has indicated that a final rule could be published as early as April 1, 2024. *Continued on page 3.*

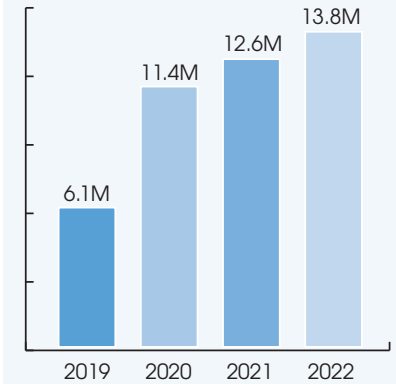
Medicare to Add HbA1c to Diabetes Test Screenings

CMS has finalized a rule to expand coverage of diabetes screening tests for Medicare recipients to include the Hemoglobin A1c test (HbA1c). This change could easily add $100+ million in annual revenue for labs. *Full details on page 4.*

PCR-Based Microbiology Test Volumes Skyrocket

PCR-based microbiology testing (excluding Covid) is dominating test volume growth. During the three-year period from 2019-2022, Medicare Part B carrier allowed claims for PCR-based microbiology tests grew by 31% per year. Over this same three-year time frame, all other broad categories of testing fell, including toxicology (-12% per year), genetic testing (-7%), anatomic pathology (-3%) and clinical lab tests (-3%). *Full details on page 7.*

Medicare Part B Allowed Test Volume for PCR-Based Microbiology Tests*



*Includes 35 codes for PCR-based testing (excludes Covid testing)
Source: *Laboratory Economics* from CMS

Versant Diagnostics Acquires Dahl-Chase Pathology

Versant Diagnostics (Grapevine, TX) has acquired Bangor, Maine-based Dahl-Chase Pathology Associates and its technical lab Dahl-Chase Diagnostic Services for an undisclosed sum. Dahl-Chase, which is the biggest pathology group in Maine, has 81 employees, including 15 board-certified pathologists. Dahl-Chase provides pathology services to 18 of the total 36 hospitals in Maine as well as hundreds of physician clients. *More details on page 2.*

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VERSANT DIAGNOSTICS ACQUIRES DAHL-CHASE PATHOLOGY (*cont'd from page 1*)
Dahl-Chase, which was founded in 1971, had been 100% owned by its pathologists. The President of Dahl-Chase is Scott Dufresne, MD.

In addition to full-service surgical pathology and immunohistochemistry testing, Dahl-Chase has significant flow cytometry, molecular diagnostics and HPV testing volumes.

Dahl-Chase's biggest client is Northern Light Health (NLH-Brewer, ME), an integrated health system with nine hospitals. Quest Diagnostics acquired NLH's clinical lab outreach assets in March 2023 (see *LE*, December 2022). In addition, Quest now provides laboratory management services for NLH's hospital labs, along with its cancer center lab at Northern Light Cancer Care in Brewer, Maine. The Quest deal did not affect anatomic pathology services provided to NLH by Dahl-Chase.

Financial advisory services to Dahl-Chase were provided by Advanced Strategic Partners (Sunny Isles Beach, FL) in the transaction.

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 manages more than 50 pathologists at six practices, has $100 million in financing (both equity and debt) from Iron Path Capital (Nashville, TN).

In addition, Versant currently has two pathology groups with a combined 9 pathologists under letters of intent (LOI) that it should finalize by the end of the year, according to Rob Albert, Chief Development Officer at Versant.

Versant is acquiring pathology practices and then seeking to add volume through increased sales and marketing and the use of digital pathology.

Versant Diagnostics Acquisition History

Acquisition Date	Laboratory Name	# Pathologists
Oct-23	Dahl-Chase Pathology (Bangor, ME)	15
May-23	PRW Laboratories (Charlottesville, VA)	8
Jun-22	Pathology Consultants of Chicago (Chicago, IL)	1
Jun-22	Elgin Laboratory Physicians (Elgin, IL)	1
Oct-21	Alliance Pathology Consultants (Elk Grove Village, IL)	15
Oct-21	Addison Central Pathology (Chicago, IL)	12

Source: *Laboratory Economics*

EDGC Buys GDXLab in Colorado

South Korean genomics company EDGC (Eone Diagnomics Genome Center) has acquired GDXLab (Englewood, CO), a CLIA-certified lab that specializes in pharmacogenetics, cardiac genetic risk testing and PCR-based test panels for urinary tract infections and respiratory pathogens. GDXLab was founded in 2014 by its CEO Min-Jeong Kim, PhD.

Through its newly acquired U.S. lab, EDGC is planning to launch its cancer test, OncoCatch-E, as a laboratory-developed test in early 2024. OncoCatch-E is an epigenetic blood-based test for early detection of colorectal, lung, breast and gastric cancers. EDGC is also in early talks with the FDA about regulatory pathways for marketing clearance for OncoCatch-E.

EDGC is an international joint venture established in 2013 between EONE Laboratories in South Korea and Diagnomics (San Diego), a CAP-accredited lab specializing in genetic testing services.

FDA WON'T EXTEND COMMENT PERIOD (*cont'd from page 1*)
The FDA estimates that there are approximately 12,000 U.S. labs performing high-complexity testing and that 10% of these are marketing LDTs. These 1,200 labs are currently offering 80,400 LDTs and 7,776 new LDTs are coming to the market each year. The FDA estimates that labs will generate $28.6 billion of revenue from LDTs in 2023.

One of the biggest concerns is the FDA's capacity to review and process as many as 80,000+ LDT applications over the next few years. For example, the FDA gave marketing authorization to a grand total of only 765 medical devices, including lab tests, in 2022, according to the FDA's Center for Devices and Radiological Health 2022 Annual Report. The FDA's ability to process tens of thousands of LDT applications in a timely manner, even with the help of third-party reviewers, is doubtful.

During an October 24 call with investors, Jim Davis, Chief Executive of Quest Diagnostics, said that Quest agrees with the long-standing assertion of the American Clinical Laboratory Assn. (ACLA), "that the FDA does not have the statutory authority to unilaterally regulate LDTs under its existing medical device authority." Davis noted that by volume, LDTs account for less than 10% of Quest's overall testing business. Quest performs the majority of its LDT testing at three ISO-certified labs, including San Juan Capistrano, CA; Chantilly, VA; and Lewisville, TX.

On an October 26 conference call, Labcorp CEO Adam Schechter said that LDTs account for less than 5% of Labcorp's volume and less than 10% of its testing revenue. "If you look at the rigor that we go through with our laboratory-developed tests, we think we do the vast majority of what they [FDA] would be asking for anyway." Schechter said FDA regulation could have unintended consequences. LDTs "are sometimes the most important test for new specialty areas. And getting those tests to patients quickly is what's most important."

One group in favor of LDT regulation is AdvaMed (Washington, DC), whose members include Abbott, BD, Bio-Rad Laboratories, bioMerieux, Hologic, Illumina and Roche. "We like the rule….This is really about making sure there's a level playing field when you're talking about diagnostics tests and having everything go through a similar pathway," said AdvaMed CEO Scott Whitaker at an October 10 press conference. "Either you raise the regulatory standard, or you lower the regulatory standard, but you do it across the board without stifling innovation," he said.

The last major effort by the FDA to formally regulate LDTs came in October 2014, when the agency issued draft guidance. But after collecting comments and facing two years of stiff opposition, the agency chose not to issue final guidance. One of the strongest critics was ACLA, which challenged the FDA's authority over the tests by filing a citizen petition and making clear its intent to sue if necessary.

Estimated Number of Labs and LDTs Affected by FDA's Proposed Rule

	Low Estimate	*Central Estimate (Primary)*	*High Estimate*
Number of Affected Labs	600	1,200	2,400
Number of Affected LDTs Currently on the Market	40,200	80,400	160,800
Number of New LDTs Per Year	3,888	7,776	15,552
LDT Revenue for 2023	$27.2 billion	$28.6 billion	$45.3 billion

Source: FDA (Docket No. FDA-2023-N-2177)

MEDICARE TO ADD HBA1C TO DIABETES TEST SCREENINGS (*cont'd from page 1*)

Currently, Medicare coverage for diabetes screening tests under Part B is limited to two types of tests: the fasting plasma glucose test (CPT 82947) and the glucose tolerance test (CPT 82950 & 82951). CMS finalized its proposal to expand coverage of diabetes screening tests to include the HbA1c test (CPT 83036) in its Medicare Physician Fee Schedule Rule for 2024.

The HbA1c test evaluates the average amount of glucose in the blood over the past 8-12 weeks. HbA1c tests are commonly used in clinical practice for diagnosis of diabetes and with this update, CMS aligns with the recommendations of the U.S. Preventative Services Task Force and the American Diabetes Association.

Increased Frequency for Diabetes Screening

CMS has also expanded and simplified its frequency limitations for diabetes screening. Currently, diabetes screening tests are allowed two times in 12 months for a patient with a pre-diabetes diagnosis and once every 12 months for anyone who is not diagnosed. CMS will now allow screening tests twice every 12 months for all Medicare beneficiaries.

Estimated Additional Annual Spending

CMS has estimated that approximately 7.6 million additional HbA1c tests for diabetes screening will be billed in calendar year 2024, resulting in approximately $68.5 million in additional annual expenditures for the Medicare Part B program. However, this estimate does not account for increased utilization of preventive screening services. It also does not account for increased diabetes testing among Medicare Advantage members. All told, *Laboratory Economics* estimates that the changes will result in more than $100 million of additional annual revenue for labs.

Which Labs will Benefit?

The biggest diabetes testing lab is Quest Diagnostics, which performed 2.9 million diabetes tests (CPT 82947, 82950, 82951 & 83036) for Medicare Part B patients in 2021 (the latest year of available data). Labcorp was next with Part B volume of 2.8 million tests; followed by Sonic Healthcare USA, 471,448 tests; and Sonora Quest Labs, 185,568 tests.

Top 12 Diabetes Testing Labs by Medicare Part B Volume*

Laboratory	Location	Part B Diabetes Test Volume
Quest Diagnostics	National	2,901,268
Labcorp	National	2,776,558
Sonic Healthcare USA	National	471,448
Sonora Quest Labs	Phoenix, AZ	185,568
Ascend Clinical	Sunnyvale, CA	183,468
Spectra Laboratories	Rockleigh, NJ & Southaven, MS	181,615
BioReference Labs	National	134,492
Northwell Health Laboratories	New Hyde Park, NY	123,788
Total Renal Laboratories	Deland, FL	119,010
PathGroup Labs	Nashville, TN	101,430
American Health Associates	Davie, FL & Cincinnati, OH	98,567
ACL Laboratories	West Allis, WI	89,194

*Includes Medicare Part B test volume for CPT 82947, 82950, 82951 & 83036; excludes panel tests
Source: Medicare Part B carrier data for 2021

Medicare PFS Final Rule Cuts Pathology Rates by 2-3% Next Year

Global rates for high-volume surgical pathology services (CPT 88305, 88307, 88331 & G0416) will decrease by 2-3% next year under the Final Medicare Physician Fee Schedule released by CMS on November 2.

Most of the decrease is related to an adjustment to the conversion factor (CF) for 2024. The CF —the dollar multiplier used to convert adjusted relative value units into payment amounts for physician services—will be 32.74 in 2024, or 3.4% below the 33.89 CF for 2023. CMS finalized the evaluation and management add-on code, G2211, causing budget neutrality adjustments that will negatively affect pathologists and other specialties in 2024. Primary care physicians and nurse practitioners will benefit.

Surgical Pathology-CPT 88305

The global rate for CPT 88305—the highest volume pathology code—is set to fall by 2% to $70.40 in 2024. The professional rate for 88305 will fall by 3% to $35.36, while the technical component will decrease by 1% to $35.04.

Immunohistochemistry

The global rate for CPT 88342 (IHC, first stain procedure) is set to rise by 3% to $104.13; professional interpretation down 3% to $33.07; technical component up 6% to $71.05.

The global rate for CPT 88341 (IHC, additional slide) is set to increase by 2% to $89.06; professional interpretation down 5% to $26.52; technical component up 5.5% to $62.54.

Potential for a Last-Minute Fix

There is the potential for Congress to pass legislation before the end of the year that would lessen the reduction to the conversion factor in 2024.

Final Medicare Rate Changes for Key Pathology Codes for 2024

CPT/HCPCS	Short Description	Proposed 2024[1]	Actual 2023[2]	Proposed Rate % Change
88305-Global	Level IV, tissue exam by pathologist	$70.40	$71.84	-2.0%
88305-26	Level IV, tissue exam by pathologist	35.36	36.60	-3.4%
88305-TC	Level IV, tissue exam by pathologist	35.04	35.24	-0.6%
88307-Global	Level V, tissue exam by pathologist	282.91	292.79	-3.4%
88307-26	Level V, tissue exam by pathologist	77.60	80.99	-4.2%
88307-TC	Level V, tissue exam by pathologist	205.31	211.80	-3.1%
88331-Global	Pathology consult during surgery	99.21	102.68	-0.8%
88331-26	Pathology consult during surgery	58.61	61.00	-1.5%
88331-TC	Pathology consult during surgery	40.60	41.68	0.4%
88341-Global	Immunohistochemistry (Add'l stain)	89.06	87.09	2.3%
88341-26	Immunohistochemistry (Add'l stain)	26.52	27.79	-4.6%
88341-TC	Immunohistochemistry (Add'l stain)	62.54	59.30	5.5%
88342-Global	Immunohistochemistry (1st stain)	104.13	100.98	3.1%
88342-26	Immunohistochemistry (1st stain)	33.07	34.23	-3.4%
88342-TC	Immunohistochemistry (1st stain)	71.05	66.76	6.4%
G0416-Global	Prostate biopsy, any method	356.58	363.27	-1.8%
G0416-26	Prostate biopsy, any method	168.31	174.86	-3.7%
G0416-TC	Prostate biopsy, any method	188.28	188.41	-0.1%

Note: Rates presented in table are national non-facility rates (unadjusted for geographic location)
[1]Payments based on proposed 2024 conversion factor of 32.7442; [2]Payments based on the 2023 conversion factor of 33.8872
Source: *Laboratory Economics* from CMS and College of American Pathologists

CorePlus Expands Use of AI Tools to Routine Cancer Diagnosis

Back in June 2020, CorePlus Servicios Clínicos y Patológicos LLC (Carolina, Puerto Rico) became the first independent lab in the Americas to begin using AI-assisted pathology for prostate cancer diagnostics (see *LE*, October 2020). CorePlus is a CLIA-certified full-service pathology laboratory with 116 employees, including six pathologists, that process 100,000 patient accessions per year. This month we got in touch with CorePlus President Mariano de Socarraz to get an update on its expanded use of AI.

Mariano de Socarraz

When did CorePlus transition to digital pathology?
We began validation for digitizing slides using 3DHISTECH scanners in mid-2019. And by early 2020 our pathologists were reading digitized whole slide images for all our pathology cases, including all routine histopathology and stains. Our pathologists review images and sign-out cases—either at home or the office—from Dell UltraSharp Ultrawide monitors.

And how did you get involved with AI-assisted pathology?
In mid-2020, we began using an AI algorithm developed by Israel-based Ibex Medical Analytics as a quality control check on digitized prostate tissue slides. The AI was used as a second opinion on all pathologist interpretations of prostate cases. Over the course of three years, the AI ran on approximately 10,000 prostate biopsy cases and found 74 missed cancer cases and corrected the grading on another 76 cases. This enabled these 150 patients and their doctors to develop optimal treatment plans based on accurate diagnosis.

The AI excels at finding small cancers, including perineural invasion. It has also standardized our lab's Gleason scoring for grading prostate cancer, which can vary by pathologist.

Early in 2021, we also began running the Ibex AI for quality control on our breast cancer cases. Over the course of almost three years, it ran on about 3,000 cases and found two missed cancer cases.

When did you begin applying AI at the front end to help with primary diagnosis?
CorePlus pathologists recently began using AI as a front-end tool to assist with primary diagnosis of prostate and breast tissue cases. Using heatmaps, the AI highlights cancer and other morphologic features on digitized slide images so that our pathologists can focus their time on the most challenging areas of interest.

What has been your return on investment (ROI) for digital pathology and AI?
We estimate that our pathologist's productivity has increased by 25% with improved accuracy. It's helped us eliminate false negatives, which can average 3-5% for uropathologists and 13-15% for general pathologists. This has raised professional satisfaction among our pathologists and recently helped us recruit a new pathologist.

Will you apply AI-based algorithms to other cancers?
Yes, we are planning to soon start using Ibex algorithms on the front end for gastric tissue biopsies and for HER2 immunohistochemistry scoring in breast cancer. We are also evaluating an AI tool from Techcyte for use as a quality control check to review 100% of our cervical cytology cases.

What are your thoughts on the potential for reimbursement of digital pathology and AI?
There is a very real potential for both digital pathology and AI reimbursement, but we as the digital pathology and AI community need to work on communicating the value of digital pathology and AI to payers as well as making sure that they understand the resources required to transform the practice of pathology for the benefit of patients and payers. Every new technology has to do this. Digital pathology and AI are no different.

PCR-BASED MICROBIOLOGY TEST VOLUMES SKYROCKET (*cont'd from page 1*)
Eighteen of the top 25 fastest-growing lab tests over the period 2019-2022 were PCR-based tests. Topping the list was CPT 87631 (respiratory virus 3-5 targets), which went from 19,653 Medicare Part B allowed services in 2019 to 133,411 in 2022 (89% per year).

The second fastest-growing test was a non-PCR test. CPT 87400 (Influenza A/B antigen) grew by 72% per year to reach 52,249 Part B tests in 2022.

CPT 87541 (Legionella pneumophila) grew by 65% per year to reach 103,692 Part B tests in 2022.

Top 25 Fastest-Growing Lab Tests by Medicare Part B Carrier Allowed Volume, 2019-2022

CPT CODE	Description	Technique	2022 Medicare Part B Volume	2019 Medicare Part B Volume	3-Year CAGR
87631	Resp Virus 3-5 Targets	PCR	133,411	19,653	89.4%
87400	Influenza A/B Antigen	Immunoassay	52,249	10,273	72.0%
87541	Legionella Pneumophila	PCR	103,692	23,058	65.1%
87556	M. Tuberculosis	PCR	37,434	10,908	50.8%
87481	Candida	PCR	1,426,676	432,924	48.8%
87651	Strep A	PCR	362,705	115,681	46.4%
87150	Culture Typing by PCR	PCR	1,174,956	375,045	46.3%
87551	Mycobacteria	PCR	40,786	13,022	46.3%
87641	Methicillin Resistant-Staph	PCR	336,815	123,852	39.6%
87640	Staph A	PCR	508,811	202,502	36.0%
87798	Detect Agent-Not Otherwise Specified	PCR	6,406,659	2,591,912	35.2%
87500	Vanomycin	PCR	389,366	166,758	32.7%
87502	Influenza	PCR	254,501	109,240	32.6%
87653	Strep B	PCR	454,592	196,198	32.3%
84182	Protein Western Blot Test	Western Blot	35,704	17,656	26.5%
87801	Detect Agent; Multiple Organisms	PCR	532,132	274,081	24.8%
87581	Mycoplasma Pneumoniae	PCR	152,345	79,901	24.0%
81479	Unlisted Molecular Pathology	Genetic	201,721	109,555	22.6%
83020	Hemoglobin Electrophoresis	Pathology	30,197	16,472	22.4%
87529	Herpes Simplex Virus (HSV)	PCR	171,315	96,397	21.1%
87486	Chlamydia Pneumoniae	PCR	142,125	80,724	20.8%
83993	Calprotectin Fecal	Immunoassay	94,335	53,991	20.4%
87532	Herpes Virus-6	PCR	30,460	17,711	19.8%
83935	Osmolality; Urine	Freezing Point Depression	67,193	39,291	19.6%
88381	Microdissection Manual	Pathology	56,458	34,046	18.4%
	Total for Top 25 Tests		**13,196,638**	**5,210,851**	**36.3%**

Source: Medicare Part B Carrier Data, 2019-2022

Cleveland Clinic Leads in PCR-Based Testing

Among all hospital-based labs in 2022, **The Cleveland Clinic Main Campus** (Cleveland, OH) performed the most PCR-based tests, according to data from the Medicare Outpatient Prospective Payment System (OPPS). Cleveland Clinic performed a total of 43,116 Medicare outpatient/outreach PCR-based tests in 2022. Its highest volume PCR-based tests included HCPCS U0003 (Covid-19 amplified probe), 10,741 tests; CPT 87636 (Covid-19 and influenza A&B amplified probe), 8,660 tests; and CPT 87497 (Cytomegalovirus, quantification), 6,421 tests.

New York Presbyterian (New York City) was a close second with 41,550 Medicare outpatient/outreach PCR-based tests in 2022. Its highest volume PCR-based test was CPT 87799 (Infectious agent detection by nucleic acid, not otherwise specified; quantification), 10,358 tests.

Stanford Hospital (Stanford, CA) had 37,901 Medicare outpatient/outreach PCR-based tests in 2022. Its highest volume PCR-based test was HCPCS U0004 (Covid-19, high throughput) at 21,153 tests.

Top 25 Hospital Labs by Medicare Outpatient/Outreach PCR Test Volume* for 2022

Hospital Name	*Location*	*Total OPPS PCR Test Volume**
The Cleveland Clinic Main Campus	Cleveland, OH	43,116
New York Presbyterian/Weill Cornell Medical Center	New York, NY	41,550
Stanford Hospital	Stanford, CA	37,901
Northwestern Memorial Hospital	Chicago, IL	33,482
Griffin Hospital	Derby, CT	32,957
Evanston Hospital	Evanston, IL	30,985
Yale New Haven Hospital	New Haven, CT	27,454
The University of Texas M.D. Anderson Cancer Center	Houston, TX	24,281
Ronald Reagan UCLA Medical Center	Los Angeles, CA	24,104
Memorial Sloan Kettering Cancer Center	New York, NY	23,900
Massachusetts General Hospital	Boston, MA	23,835
Loyola University Medical Center	Maywood, IL	22,338
Brigham and Women's Hospital	Boston, MA	21,723
UC San Diego Medical Center	San Diego, CA	20,752
University of Michigan Medical Center	Ann Arbor, MI	20,122
Tisch Hospital	New York, NY	20,118
Berkshire Medical Center	Pittsfield, MA	20,010
Strong Memorial Hospital	Rochester, NY	19,383
UCSF Helen Diller Medical Center at Parnassus Heights	San Francisco, CA	18,606
Cedars-Sinai Medical Center	Los Angeles, CA	18,298
Stony Brook University Hospital	Stony Brook, NY	17,292
Northwestern Medicine Central DuPage Hospital	Winfield, IL	17,108
Northwest Community Hospital	Arlington Heights, IL	16,885
Carolinas Medical Center	Charlotte, NC	15,801
The Mount Sinai Hospital	New York, NY	15,785
Total for all 2,614 hospitals		**4,518,049**

*Based on 40 CPT codes for PCR-based testing (e.g., 87481, 87497, 87507, U0003, U0004, etc.)

Source: *Laboratory Economics* from Medicare Outpatient Prospective Payment System (OPPS) for 2022

Pathnostics Gets NYS Approval for PCR-Based UTI Test

Pathnostics (Irvine, CA) has gained approval from the New York State Department of Health (NYSDOH) for its Guidance UTI test, which is used to quickly diagnose recurrent and complicated urinary tract infections (UTIs).

The laboratory-developed test uses PCR to identify 27 individual organisms and three bacterial groups, as well as 32 resistance genes and six classes of antibiotics.

There are an estimated 10+ million new and recurrent UTI cases each year in the United States, resulting in more than 600,000 hospitalizations, according to Mohit Mathur MD, PhD, Chief Medical Officer at Pathnostics.

Compared with standard urine culture testing, which can take three to five days to generate results, the Guidance UTI test offers more accurate results within a day after receiving samples in the lab. As a result, the test has been shown to lower emergency and urgent care visits and patient hospitalizations, as well as initial antibiotic prescriptions selected in the absence of definitive lab test results.

Quest Diagnostics Launches $55 At-Home Phlebotomy Service

Quest Diagnostics is now offering patients the option to have their specimens collected at home through a new service branded Quest Mobile. The service will utilize the 5,000 phlebotomists that work at Quest's life insurance testing subsidiary ExamOne (Lenexa, KS). Patients will pay an out-of-pocket $55 collection fee at the time of scheduling. Quest says that it is negotiating with health plans to arrange commercial pricing to eliminate an out-of-pocket cost for patients.

Labcorp Paid $157 Million for Tufts Medicine Outreach Business

Labcorp's latest quarterly financial report (ended Sept. 30, 2023) showed that it paid $157 million in cash to acquire the clinical lab outreach business of Tufts Medicine (see *LE*, August 2023). Other previously undisclosed acquisition prices paid by Labcorp include its $110 million cash purchase of Providence Oregon's clinical lab outreach business (see *LE*, June 2023) and its $108 million cash buy of Jefferson Health's clinical lab outreach assets (see *LE*, May 2023).

Most health systems are struggling financially—primarily because of wage pressure and inflation. At the same time, the two biggest commercial labs continue to seek added revenue from acquisitions at valuations as high as 2-3x annual revenue.

Recent Hospital Lab Outreach Acquisition Prices

Date	Buyer	Hospital Lab Target	Purchase Price ($ mill)
Pending	Labcorp	Legacy Health outreach lab (Portland, OR)	$115E
Sep-23	Labcorp	Tufts Medicine outreach lab (Boston, MA)	$157
Jun-23	Labcorp	Providence Oregon outreach lab (Portland)	$110
May-23	Labcorp	Jefferson Health outreach labs (Philadelphia)	$108
Apr-23	Quest Diagnostics	NewYork-Presbyterian outreach lab (New York City)	$275
Mar-23	Quest Diagnostics	Northern Light Health outreach lab (Bangor, ME)	$31
Nov-22	Quest Diagnostics	Summa Health LabCare Plus (Akron, OH)	$38
Oct-22	Labcorp	Ascension Health outreach labs (St Louis, MO)	$424

Source: Labcorp and Quest Diagnostics

Genomic Health to Pay $32.5M Settlement; Whistleblowers Get $5.7M

Genomic Health (Redwood City, CA), a subsidiary of Exact Sciences, has agreed to pay $32.5 million to resolve allegations that it violated the False Claims Act by improperly billing Medicare for expensive cancer tests. The two whistleblowers (Samuel Caughron, MD, and Kirsten Arndt-Hutson) that prompted the U.S. Department of Justice's investigation will share $5.7 million from the announced settlement.

The DOJ alleged that Genomic Health conspired with and encouraged hospitals and physicians to cancel and reorder Oncotype DX tests to circumvent the 14-Day Rule. The 14-Day Rule prohibits labs from separately billing Medicare for covered tests if a physician ordered the test within 14 days of the patient's discharge from a hospital stay or outpatient procedure.

Medicare reimbursement for the Oncotype DX test (CPT 81519) is $3,873.

"We are pleased to resolve this matter related to legacy policies at Genomic Health prior to its 2019 acquisition by Exact Sciences," according to a statement from Exact Sciences.

Viome Gets CVS Deal to Sell Gut Health Test

Viome Life Sciences (Bellevue, WA) recently began marketing its Gut Intelligence Test at 200 of CVS' brick-and-mortar stores. The company's Gut Intelligence Test (list price of $259/sales price of $179) is a take home stool collection kit. Samples are sent to Viome's CLIA-certified lab in Bothell (outside of Seattle). Test results are emailed to consumers in 2-3 weeks.

Viome's Gut Intelligence Test utilizes mRNA sequencing to analyze microorganisms (e.g., bacteria, viruses and fungi) in a person's gastrointestinal tract. Microorganisms are believed to play a role in chronic conditions such as inflammatory bowel disease.

The Viome test report includes 20+ gut health scores that span inflammatory activity, metabolic fitness and microbiome-induced stress. Viome also provides personalized food and supplement recommendations advertised to "enhance nutrient uptake" and "slow biological aging by addressing activities contributing to inflammation throughout your body." Viome sells its own line of supplements and probiotic blend drink mixes.

Other direct-to-consumer tests offered by Viome include its Full Body Intelligence Test (list price of $399/sales price of $299) and Oral Health Intelligence Test (list price of $259/sales price of $179).

Viome raised $86.5 million from a Series C funding round in August. Viome says the funding is being used to support further R&D and retail expansion. The company has raised a total of $175 million to date. Major investors include Khosla Ventures, Bold Capital and WRG Ventures.

Viome was founded by its CEO Naveen Jain, age 64, in 2016. Jain is also Founder and Executive Chairman of Moon Express (Mountainview, CA), which is "developing a robotic lunar lander to explore and mine the moon for planetary resources that will be the key to securing humankind's future." *Note: We are not making this up.*

Evvy Raises $14M for Vaginal Microbiome Testing

Evvy (New York City) has raised $14 million from a Series A funding round led by Left Lane Capital. Other investors included General Catalyst and Labcorp Venture Fund. Evvy markets a vaginal microbiome test directly to consumers at a price of $99. Testing is performed at MicroGenDX (Orlando, FL). Priyanka Jain (daughter of Naveen Jain—see above) is Co-Founder & CEO of Evvy.

23andMe to Require Two-Step Verification Following Data Breach

The genetic testing company 23andMe (South San Francisco, CA) says that it will now require all customers to utilize email 2-step verification (2SV) as an added layer of protection for their accounts. This follows a well-publicized cyber-attack that exposed the name, sex, birth year, and some details about genetic ancestry results for some five million customer accounts.

The data breach occurred around October 1. Hackers obtained customer info by "credential stuffing:" the practice of using one set of leaked usernames and passwords from a previous data breach on another website in hopes that people have reused passwords.

On an October 8 conference call, 23andMe executives said they cannot yet estimate the costs of dealing with the cyber-attack.

The data breach is small potatoes compared with bigger problems at 23andMe. The company has accumulated $1.7 billion in losses since being founded in 2006.

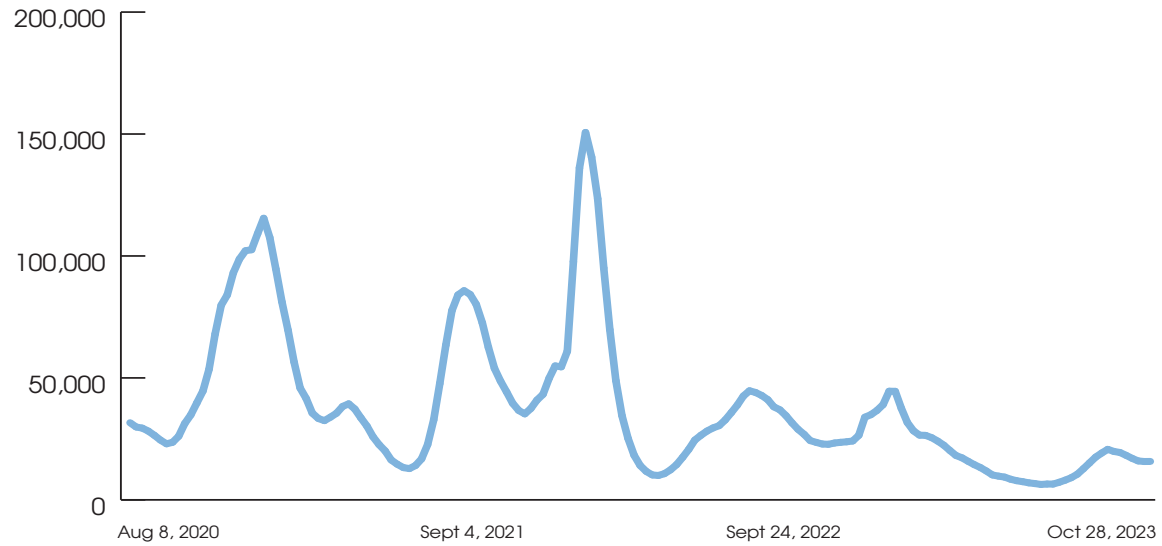
23andMe generates its revenue primarily by marketing genetic test services for health risks and ancestry directly to consumers. It subcontracts lab testing services to third-party CLIA-certified labs, including Labcorp. In addition, the company earns revenue by selling anonymized DNA and demographic data to pharmaceutical companies, including GlaxoSmithKline (GSK).

Most recently, 23andMe reported a net loss of $180 million for the six months ended Sept. 30, 2023, versus a net loss of $156 million for the same period a year earlier; revenue fell by 21% to $111 million.

This Year's Covid-19 Season is Looking Mild So Far

Covid-19 hospital admissions have begun slumping again after an expected back-to-school uptick in early September. Hospitalizations totaled 15,745 for the week ended October 28, according to the latest available data from the CDC. Hospitalizations are likely to tick up during the impending holiday season, but nothing like the weekly peak seen in January 2022 when more than 150,000 Covid-19 admissions were recorded.

Weekly Covid-19 Hospital Admissions: Aug. 2020 – Oct. 2023



Source: CDC

Lab Stocks Down 19% Year-to-Date In 2023

Twenty-four lab stocks have dropped by an unweighted average of 19% year to date through November 13. In comparison, the S&P 500 Index is up 15% year to date. The top-performing lab stocks thus far in 2023 are NeoGenomics, up 74%; Natera, up 21%; and Exact Sciences, up 20%. Labcorp shares are up 1% (after adjusting for spinoff of Fortrea) and Quest Diagnostics is down 15%.

Company (ticker)	Stock Price 11/13/23	Stock Price 12/30/22	2023 Price Change	Enterprise Value ($ millions)	Revenue for Trailing 12 mos. ($ millions)	Enterprise Value/ Revenue
NeoGenomics (NEO)	$16.08	$9.24	74%	$2,210	$575	3.8
Natera (NTRA)	48.54	40.17	21%	5,120	989	5.2
Exact Sciences (EXAS)	59.27	49.51	20%	12,650	2,406	5.3
Myriad Genetics (MYGN)	16.49	14.51	14%	1,570	734	2.1
Opko Health (OPK)	1.28	1.25	2%	1,140	867	1.3
Interpace Biosciences (IDXG)	1.10	1.04	6%	60	38	1.6
Labcorp (LH)	204.41	202.30	1%	23,100	15,071	1.5
Sonic Healthcare (SHL.AX)*	29.96	29.97	0%	16,520	8,170	2.0
Veracyte (VCYT)	22.95	23.73	-3%	1,430	343	4.2
Fulgent Genetics (FLGT)	26.24	29.78	-12%	-52	286	NA
Enzo Biochem (ENZ)	1.22	1.43	-15%	-13	31	NA
Quest Diagnostics (DGX)	132.35	156.44	-15%	19,820	9,297	2.1
DermTech Inc. (DMTK)	1.48	1.77	-16%	35	14	2.4
Guardant Health (GH)	22.63	27.20	-17%	2,750	536	5.1
Castle Biosciences (CSTL)	17.72	23.54	-25%	247	192	1.3
Aspira Women's Hlth (AWH)	3.72	4.95	-25%	40	9	4.4
CareDx (CDNA)	7.92	11.41	-31%	167	297	0.6
Exagen (XGN)	1.46	2.40	-39%	19	53	0.4
Biodesix (BDSX)	1.30	2.30	-43%	125	44	2.8
ProPhase Labs (PRPH)	4.54	9.63	-53%	98	63	1.6
Psychemedics (PMD)	2.28	4.90	-53%	15	23	0.6
Invitae (NVTA)	0.52	1.86	-72%	1,390	482	2.9
GeneDx (WGS)	1.24	8.71	-86%	-8	207	NA
Biocept (BIOCQ)	0.22	15.90	-99%	5.5	1	3.9
Totals & Averages			**-19%**	**$88,437**	**$40,728**	**2.2**

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

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