

LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

Grail Begins Selling Multi-Cancer Liquid Biopsy Test

Grail Inc. (Menlo Park, CA) has started marketing its Galleri blood test as a multi-cancer screening test for asymptomatic individuals over age 50. The test is being launched as a laboratory developed test (LDT) that will be performed at Grail’s CLIA-certified and CAP-accredited laboratory in Menlo Park, California. The list price for Galleri is \$949.

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NJ Lab Sues UnitedHealth For Covid-19 Test Payments

Genesis Laboratory Management LLC (Oakhurst, NJ) is suing UnitedHealth Group, accusing the company and its Oxford Health Plans unit of not covering claims for Covid-19 tests. The lawsuit was filed on June 2 in the U.S. District Court for the District of New Jersey (case: 3:21-cv-12057). Genesis says that UnitedHealth has not paid it for 51,000 claims for Covid-19 testing and made burdensome and unjustified requests for medical records. *Full details on page 3.*

ACLA Files For Appeal In PAMA Lawsuit

The American Clinical Laboratory Assn. (ACLA) has filed a notice of appeal in its lawsuit against the U.S. Department of Health and Human Services (HHS) over the implementation of the Protecting Access to Medicare Act (PAMA), which sets Medicare CLFS rates based on private-payer rates. ACLA, which is represented by King & Spalding LLP (Washington, DC), is now negotiating with HHS attorneys on a briefing schedule that must be finalized by the U.S. Court of Appeals for the District of Columbia. *Continued on page 9.*

Eurofins Big Winner In School Testing Contract Awards

Eurofins Clinical Enterprise Inc. (Framingham, MA) has won government contracts to perform Covid-19 testing at K-8 schools, homeless shelters and underserved populations in the Northeast and Southern regions. The contract awards were announced by the U.S. Department of Health & Human Services (HHS), in coordination with the U.S. Department of Defense (DoD), on May 25. In addition, Battelle (Columbus, OH) won a contract for the Midwest region and PerkinElmer Health Sciences (Waltham, MA) won the Western region. The combined value of the four regional contracts is \$650 million and will run through September 2023. *More details on page 2.*

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Eurofins Big Winner In School Testing Contract Awards (*cont'd from p. 1*)

A total of 187 applicants had vied for the regional contracts. Noticeably absent from the award winners were the nation's largest commercial lab companies, including Labcorp, Quest Diagnostics, Sonic Healthcare USA and OPKO's BioReference Labs.

HHS/DoD had originally been scheduled to announce the contract awards on April 27, which was pushed back to May 13, and then delayed again until May 25. The delays mean that Covid-19 testing under this program is not likely to be meaningful until the start of the next school year in late August/early September.

Under the contracts, Eurofins, Battelle and PerkinElmer will each need to contact school districts in their regions and convince them to establish Covid-19 screening programs. Pooled Covid-19 PCR testing is expected to be the primary method used. No third parties, such as schools or health insurers, will be billed under this government-funded program.

However, over the past 12 months, many school districts have already established testing programs through private contracts with other labs like Quest and Labcorp. The desire to start new testing programs may also be dampened given the big declines in new cases, hospitalizations and deaths from Covid-19 since the national peak in early January. On a national basis, total Covid-19 PCR test volumes have declined from an average of more than two million tests per day in early January to less than 750,000 tests per day in mid-June.

Eurofins says it will implement pooled Covid-19 PCR testing at schools in communities in its two contract award regions (combined 26 states). Eurofins says that its high ratio pooling (24 samples per pool) will reflex pooled samples that test positive to individual PCR tests. Eurofins expects to test up to 24.6 million people under the contract. "We have more than enough capacity to meet these demands across our 20 U.S. CLIA labs," according to a Eurofins spokesperson. Eurofins has partnered with Affinity Empowering Inc. (Alexandria, VA), which will help provide on-site sample collection services at schools and other locations.

Battelle says that outreach and coordination in its Midwest region (16 states) will begin immediately while testing in schools and other congregate centers is to begin this July. Battelle will subcontract Covid-19 testing to CLIA-certified labs—specific lab partners have not yet been announced. Battelle's goal is to test 750,000 people per week. Battelle is a not-for-profit organization founded in 1929 that conducts research and development for government and commercial clients.

PerkinElmer was selected for the Western region (8 states). Under a controversial no-bid contract with the State of California, PerkinElmer manages and staffs a big new 134,000 sq. foot Covid-19 testing facility in Valencia (north of Los Angeles). California spent \$120 million to build and equip the Valencia Branch Laboratory (VBL), which opened on November 1, 2020. VBL has the capacity to perform up 150,000 PCR tests per day.

School Testing Regional Contract Awards

<i>Contract Winner</i>	<i>Region</i>	<i>States</i>	<i>Total Population</i>
Eurofins	Northeast	CT, DE, MA, MD, ME, NH, NJ, NY, PA, RI, VA, VT, WV	78 million
Eurofins	South	AL, AR, FL, GA, KY, LA, MS, NC, NM, OK, SC, TN, TX	110 million
Battelle	Midwest	CO, IA, IL, IN, KS, MI, MN, MO, MT, ND, NE, OH, SD, UT, WI, WY	79 million
PerkinElmer	West	AK, AZ, CA, HI, ID, NV, OR, WA	66 million

Source: U.S. Dept. of Health & Human Services

NJ Lab Sues UnitedHealth For Covid-19 Test Payments (*cont'd from p. 1*)

Genesis, which employs more than 10 pathologists, operates a CAP-accredited independent anatomic pathology and molecular diagnostics lab in northern New Jersey.

Genesis says that it has made multiple attempts to become in-network with United, but has been unsuccessful. As a result, Genesis is out-of-network (aka non-par) and does not have a contract with UnitedHealth.

At the start of the pandemic in March 2020, Genesis began Covid-19 PCR testing at a cash price of \$256.65 listed on its website as required by the CARES Act. Genesis says that it raised its cash price to \$513 in mid-April 2020 after CMS doubled its Medicare reimbursement rate for high-volume Covid-19 PCR testing to \$100.

During the early months of the pandemic in March, April and May 2020, Genesis says that United paid the majority of its claims for Covid-19 PCR tests at Genesis's billed rates of \$256.65 and then \$513. However, from June 2020 and onward, Genesis alleges that "United has been systematically denying payment."

Instead of paying Covid-19 test claims, Genesis says that "United has elected to send an unreasonable number of requests for clinical records and other supporting documents for the services that Genesis provided United's members." United demands this documentation within 30 days of its request, including physician orders, patient intake forms, copies of CLIA certificates for six years, types of equipment and reagents for testing, credentials for every onsite technical lab employee, etc., according to Genesis.

Genesis says that it has no control over whether ordering providers will comply with its documentation requests (much less within the 30-day window

demanding by United). United has far greater access to patient medical records because the source is United's own participating providers, according to the Genesis lawsuit.

The lawsuit notes that United's pre-payment review is far less prevalent when employer self-funded health plans are involved versus fully-insured plans where United's own dollars are at stake. "United's tactics are not in good faith because United is simply trying to reduce its own medical spend rather than acting out of legitimate concern that Genesis is not properly documenting its reimbursement claims," according to the complaint.

Furthermore, Genesis says that United's failure to reimburse for Covid-19 tests is in clear violation of the Families First Coronavirus Response Act (FFCRA) and CARES Act, which prohibit health plans from "imposing any cost sharing...requirements or prior authorization or other medical management requirements" in connection with Covid-19 testing.

Genesis, which is being represented by King & Spalding LLP (Atlanta, GA), is seeking compensatory damages and attorney fees. *Laboratory Economics* estimates that the amount in dispute is roughly \$26 million (51,000 claims x \$513 per test).

"We disagree with the allegations in the complaint and intend to vigorously defend ourselves in this matter," according to a statement from United.

Genesis Laboratory Cash Rates for Covid-19 Testing

CPT Code	Description	Genesis Rate	Medicare Rate
U0003	High-thruput Covid-19	\$513.00	\$100.00*
U0004	High-thruput Covid-19	\$513.00	\$100.00*
87635	Low-thruput Covid-19	\$513.00	\$51.31
86769	Covid-19 IgG antibodies	\$179.00	\$42.13
86769	Covid-19 IgM antibodies	\$119.00	\$42.13

*Medicare rate for high-thruput Covid-19 testing includes add-on payment of \$25 for meeting two-day turnaround.
Source: CMS and Genesis Laboratory

Long-Time Lab Execs Start New Pathology Lab: EmeritusDX

Robert Embree and Jason Allchin have teamed up to form a new cancer diagnostics lab named EmeritusDX (Irvine, CA). Chief Executive Embree, age 61, has been in the lab business for 30 years and was most recently co-founder and Executive Vice President of Operations at Pathnostics (Irvine, CA). Allchin, age 43, has 20 years' experience and was most recently Vice President of Operations at NeoGenomics' lab in Orange County. Below is a Q&A summary of *Laboratory Economics'* interview with Embree and Allchin in early June.



Robert Embree

Starting a pathology lab during a pandemic seems like a crazy idea. What were you thinking?

Embree: Jason and I have a long working relationship. First at US Labs (acquired by Labcorp in 2005) and then again at Pathnostics. After we both moved on from those companies, we remained friends and then bumped into each other at a birthday party last year. I casually brought up the idea of starting a new lab company and the idea gradually grew.

Allchin: We had initially considered starting an infectious disease laboratory, but by late 2020/early 2021 it was becoming clear that there was already more than enough Covid-19 testing capacity in the United States and that the pandemic wasn't going to last forever.

At the same time, we saw that some patients were having difficulty getting access to timely cancer testing, either because of limited access due to the pandemic or because lab companies had redirected their resources to focus on Covid testing. There were other variables in our decision making, but ultimately we saw the potential for a high-service, client-focused anatomic pathology lab.

Where did you get the money to open your lab and launch the company?

Embree: Initial startup costs have been roughly \$500,000 and this has come entirely out of our own pockets with no outside investors or debt. Having full control allows us to build from the ground up with a strong employee culture focused on quality and service. It also motivates us to spend every dollar carefully—an important factor in a market that has historically seen reimbursement rates erode.

Where and when did you open your laboratory?

Allchin: Our initial laboratory was opened in Costa Mesa in January. It was a modest 950 sq. feet devoted almost 100% to laboratory space. On June 1, we moved into a new building in nearby Irvine that is 4,500 sq. feet with a 60% lab/40% office split.

What's the testing focus of EmeritusDX?

Allchin: Surgical pathology and FISH testing. We're also in the process of adding molecular tests for urinary tract infections (UTIs) and genotyping tests that can help urologists select the best antibiotic for UTI treatment.



Jason Allchin

How many employees are at EmeritusDX and who is your chief pathologist?

Embree: We've currently got eight employees and expect to reach 40 by the end of the year. Our Laboratory Medical Director is Sima Fargahi, MD, who we've known and admired from her work at Plus Diagnostics, Pathnostics and, most recently, NeoGenomics.

Have there been any issues with non-compete contracts with former employers?

Allchin: Robert's non-compete with Pathnostics has expired. As for myself, I believe the target market for EmeritusDX is different from the segment that NeoGenomics services. I'd also point out that non-compete agreements that infringe on a former employee's right to earn an income are generally not enforceable under California law.

How does EmeritusDX differentiate itself from other pathology labs?

Allchin: Client service. We are extremely nimble, which means we can react much more quickly than our competitors to client needs. This includes things like customizing client requisition forms, ease of online ordering and tailored result reports.

What is your goal for TAT of results after specimen pickup?

Allchin: Anatomic Pathology will be 24-48 hours, FISH will be 48-72 hours and UTI will be 24-48 hours.

Can you describe the salesforce at EmeritusDX?

Embee: It's a top priority. We are in the process of building out our salesforce with an emphasis on recruiting experienced sales reps with existing relationships who know how to sell to urology, gastroenterology and dermatology groups.

How are you handling billing and collection?

Embee: We've contracted with VitalAxis Inc. for both our lab information management system and billing and collection. In addition, they are helping us get in-network with health insurers. Because they're paid on a percentage of cash collections, VitalAxis is incentivized to help us grow. Outsourcing these key functions also allows us to focus and invest in our lab operations, sales and client service.

Cigna Reverses Course: Will Keep Paying the PC For Clinical Lab Services

On June 7, Cigna informed the College of American Pathologists (CAP) that it plans to continue reimbursing pathologists for the professional component (PC) of clinical pathology services. A formal update from Cigna regarding the policy reversal is forthcoming soon, according to CAP.

Cigna had announced a new payment policy on April 12 whereby it would stop paying for the PC of clinical pathology services effective July 11 (see *LE*, May 2021). The change would have had the greatest impact on hospital-based pathology groups that bill Cigna for professional services they provide to hospital inpatients and outpatients that get clinical lab tests. The change would have affected hospital-based pathologists in several states, including California, Florida, Pennsylvania and Texas.

In an April 23 letter, the CAP pressed Cigna to rescind its planned policy change. The CAP noted that pathologists as directors of hospital labs spend a significant amount of time on the development and evaluation of clinical lab test instrumentation and reagents, pre- and post-analytical oversight, and compliance with all regulatory and lab accreditation standards. Several state pathology societies also sent letters to Cigna urging them to reverse course.

The CAP also cited several lawsuit results that have upheld the right for pathologists to be compensated for the PC of clinical pathology services.

Most recently, on October 23, 2020, a class action settlement was reached on favorable terms to pathologists after UnitedHealthcare stopped making payments for the PC of clinical pathology services to its out-of-network providers on its Medicaid lines of business in Florida.

The lawsuit (Palmetto Pathology Services, P.A. vs. United Healthcare of Florida) was filed in late 2017 after United stopped making payments for PC-CP to its non-par hospital-based pathologists on its Medicaid lines of business. United agreed to make past payments at 100% of Florida Medicaid Fee Schedule plus interest, and to make future payments for covered PC-CP claims in accordance with the Florida Medicaid Fee Schedule.

Grail Begins Selling Multi-Cancer Liquid Biopsy Test *(cont'd from page 1)*

The Galleri blood test can detect more than 50 types of cancer (breast, colon, head and neck, liver, lung, ovary, pancreas, etc.) from fragments of DNA shed by tumors. Launch of the LDT version coincided with the release of interim clinical study results at the American Society of Clinical Oncology (ASCO) 2021 Annual Meeting, June 4-8.

The prospective, multi-center study (dubbed Pathfinder) began in December 2019 and includes 6,629 individuals aged 50 or older. Participants are being followed for 12 months. Final study results should be available in early 2022.

In the interim analysis, an earlier version of Galleri detected 92 cancer signals from the 6,629 participants. Thirty-six of the signals were false positives, 29 were true positives and there is no current diagnostic resolution to the other 27. The positive predictive value (PPV), or the likelihood that a person has cancer when a positive test result is returned, was 44.6%. When cancer was confirmed, Galleri's first or second cancer signal origin prediction was 96.3% accurate.

"Most importantly, it can detect cancers that have no recommended screening tests today, and more than two-thirds of cancers go unscreened for this reason," said the study's presenting author Tomasz Beer, MD, Deputy Director at the Oregon Health and Science University's Knight Cancer Institute.

The FDA has given the Galleri test its breakthrough device designation. Grail is hoping to obtain full FDA clearance in 2023.

Earlier this year, Grail contracted with Quest Diagnostics to help with its national LDT rollout. Quest will perform Galleri blood draws at more than 2,200 PSC locations and through at-home visits via its ExamOne network of 5,000 mobile phlebotomists.

Testing will initially be performed at Grail's lab in northern California. Grail is in the process of building a bigger (200,000 sq. feet) laboratory in Durham, North Carolina.

Grail had filed for an IPO late last year (see *LE*, September 2020). The IPO was pulled when Illumina, which already owns 15% of Grail, made an offer to buy the whole company for \$7.1 billion. However, scrutiny from the FTC and regulators in Europe have raised doubts about whether Illumina will be able to close the deal.

Progress Update for Selected Liquid Biopsy Tests

Company	Liquid Biopsy	Use	Status	List Price
Guardant Health	Guardant360	Helps select targeted therapy	FDA cleared Aug. 7, 2020	\$6,800
Roche/Foundation Medicine	FoundationOne Liquid CDx	Helps select targeted therapy	FDA cleared Aug. 27, 2020	\$5,800
Grail Inc.		Screening for early detection	Launched as LDT June 4, 2021	\$949
Exact Sciences/Thrive	CancerSeek	Screening for early detection	FDA breakthrough device-designated	Expected \$500
Natera	Signatera	Helps select targeted therapy	FDA breakthrough device-designated	NA
Invitae/Archer DX	Stratafide	Helps select targeted therapy	FDA breakthrough device status	NA

Source: *Laboratory Economics*, EvaluateMedTech and company websites

Comparing Productivity At Quest, Labcorp And BioReference

On a weighted basis, three publicly-traded lab companies collected average revenue of \$52.73 per requisition in 2020. Average collected revenue per test was an estimated \$15.98. Results for 2020 were greatly skewed by huge Covid-19 test volumes. The three lab companies performed a total of 68.1 million Covid-19 PCR tests and 9.4 million antibody tests in 2020.

The three companies—Quest Diagnostics, Labcorp and OPKO's BioReference Labs—generated a weighted average of \$224,187 in revenue per employee in 2020. The average number of requisitions processed was 4,252 per employee, while employees processed an average of 14,031 tests. These figures are based on the total number of employees at the three companies, including all administrative, couriers, sales and marketing, and lab technical staff.

Productivity Stats at Quest, LabCorp and BioReference for 2020

2020 Financials	Quest Diagnostics	Labcorp Diagnostics*	BioReference Laboratories	Total
Annual Revenue 2020	\$9,437,000,000	\$9,253,400,000	\$1,262,242,000	\$19,952,642,000
Operating Income 2020	\$1,971,000,000	\$2,634,900,000	\$138,992,000	\$4,744,892,000
# Employees (FTEs)**	44,500	40,000	4,500	89,000
Employee Efficiency				
Avg. Annual Revenue per FTE	\$212,067	\$231,335	\$280,498	\$224,187
Avg. Annual Operating Income per FTE	\$44,292	\$65,873	\$30,887	\$53,313
Requisition Stats				
Est'd Annual Requisitions 2020	186,600,000	172,800,000	19,000,000	378,400,000
Est'd Avg. Revenue per Requisition	\$50.57	\$53.55	\$66.43	\$52.73
Est'd Avg. Operating Income per Req.	\$10.56	\$15.25	\$7.32	\$12.54
Est'd Avg. Reqs processed per FTE	4,193	4,320	4,222	4,252
Test Stats				
Est'd Annual Test Volume 2020***	615,780,000	570,240,000	62,700,000	1,248,720,000
Est'd Avg. Revenue per Test	\$15.33	\$16.23	\$20.13	\$15.98
Est'd Avg. Operating Income per Test	\$3.20	\$4.62	\$2.22	\$3.80
Est'd Avg. Tests processed per FTE	13,838	14,256	13,933	14,031
Billing Stats				
Accounts Receivable	\$1,520,000,000	\$1,515,500,000	\$257,682,600	\$3,293,182,600
Est'd Bad-Debt % (pre-ASC 606)	4% - 5%	4% - 5%	5% - 10%	5.0%
Days in AR	50 - 60	50 - 60	60 - 90	55 - 60
Revenue by Payer				
Private Patients	11.0%	9.2%	4.0%	9.7%
Medicare CLFS	8.0%	8.8%	5.2%	8.2%
Medicare PFS	1.0%	0.4%	1.0%	0.7%
Medicaid	2.0%	1.6%	1.0%	1.8%
Client Payers (physicians, hospitals, etc.)	38.0%	30.8%	50.5%	35.4%
Healthcare Insurers	37.0%	49.2%	38.3%	42.7%
Other	3.0%	0.0%	0.0%	1.4%
Covid-19 Testing				
PCR Test Volume for 2020	27,000,000	31,000,000	10,100,000	68,100,000
Antibody Test Volume for 2020	4,600,000	4,000,000	800,000	9,400,000

*Data is for Labcorp's lab testing business only. **Part-time employees counted as ½ FTE. ***Test volume stats assume an average of 3.3 tests per requisition. Source: Company reports and *Laboratory Economics*' estimates

Quest Completes Acquisition of Mercy's Outreach Lab Business

Quest Diagnostics has completed its previously announced acquisition of the clinical lab outreach business of Mercy (St. Louis, MO) in an all-cash asset transaction (see *LE*, March 2021). The purchase price has not yet been disclosed. Cain Brothers served as Mercy's transaction advisor.

Under the deal, Mercy's clinical lab outreach tests will transition to Quest's full-service laboratory in Lenexa, Kansas. Mercy's clinical lab outreach business currently operates from 29 hospital laboratories and two independent clinical laboratories serving providers and patients in Arkansas, Kansas, Missouri and Oklahoma.

Mercy will continue to wholly own and operate its hospital laboratories for tests connected to inpatient and hospital-based outpatient services.

Apollo To Buy Sun Clinical Labs For \$4 Million

Apollo Medical Holdings (ApolloMed-Alhambra, CA) has agreed to purchase a majority stake in Sun Clinical Laboratories (Sun Labs-El Monte, CA) for \$4 million in cash. The deal is expected to close within three months.

Sun Labs is a small independent routine clinical lab with 19 patient service centers located across the San Gabriel Valley in southern California. Sun Labs was founded by its CEO Francis Sun in 1980.

ApolloMed is a publicly-traded company that manages 14 independent physician associations (IPAs) with 7,000 contracted physicians located primarily in California. Apollo's IPAs have capitated contracts with insurers (Aetna, Anthem, Cigna, Humana, UnitedHealthcare, etc.) covering a total of 1.13 million members. ApolloMed, which is expanding into New York and Florida, anticipates growing to a total of 10,000 contracted physicians, two million covered lives, and \$700 million of revenue by the end of this year.

Apollo had already been using Sun Labs for testing services. "As ApolloMed expands its geographic footprint, we see Sun Labs as a core partner in this expansion, growing the business and bringing high-quality lab services to more patients across the nation," according to Kenneth Sim, MD, Chairman and Co-Chief Executive of ApolloMed.

Progenity To Close Genetics Lab To Conserve Cash

Progenity Inc. (San Diego, CA) says it will close its genetics lab in Ann Arbor, Michigan, to conserve cash and will now focus on its drug delivery technologies and therapeutics.

Progenity's Michigan lab specializes in noninvasive prenatal testing (NIPT) to determine the risk that a baby will be born with certain genetic abnormalities. Closing this lab and laying off its 374 employees will result in about \$130 million in annualized cost savings, according to Progenity.

In addition, Progenity says it's evaluating the potential to raise capital by selling its Avero Diagnostics anatomic pathology laboratory in Texas. Avero Diagnostics is nearing operating profitability with projected revenue of \$35-\$40 million for 2021, according to Progenity.

The decision to restructure comes less than one year after Progenity's IPO (see *LE*, July 2020).

As of March 31, 2021, Progenity had cash and cash equivalents of \$65 million and had accumulated losses totaling \$574 million since being formed in 2012. For the three months ended March 31, 2021, the company reported a net loss of \$32 million on revenue of \$24.5 million.

ACLA Files For Appeal In PAMA Lawsuit (*cont'd from page 1*)

ACLA originally filed its lawsuit in December 2017, claiming that HHS wrongly excluded hospital outreach labs from the first private-payer rate survey used to determine Medicare CLFS rates effective in 2018. Earlier this year, Judge Amy Berman Jackson ruled that the lawsuit is moot and dismissed the case (see *LE*, May 2021).

The appeals process will take at least several months. If the appeal is successful, the case will most likely be kicked back to Judge Jackson of the District of Columbia District Court to hear arguments and make a ruling.

MedPAC Report on PAMA Imminent

Separately, ACLA and the lab industry are awaiting a final report on PAMA from the Medicare Payment Advisory Commission (MedPAC). The LAB Act mandated MedPAC to review the methodology that CMS used to implement private-payer-based CLFS rates. The fear is that MedPAC will recommend a simplified survey that relies on the most-efficient lower-cost labs.

Lab Lobby Spending Near Record High

The Covid-19 pandemic and associated restrictions did not slow down lab industry lobbying efforts last year. Ten of the lab industry's largest trade organizations and companies spent a total of \$7.4 million on lobbying efforts in 2020, according to data from the Center for Responsive Politics (Washington, DC). Over the past seven years (2013-2020), lobby spending by the 10 lab organizations has risen by an average of 6% per year.

Individually, ACLA had the biggest lobbying budget last year at a record \$1.77 million. LabCorp (\$1.75 million) and Quest Diagnostics (\$880,000) also spent large amounts. Lobbying efforts were mostly directed at the Centers for Disease Control & Prevention (CDC), the Dept of Health & Human Services (HHS), the Centers for Medicare & Medicaid Services (CMS) and the Food & Drug Administration (FDA).

At the top of the lab industry's lobbying agenda last year were payment rates and coverage of Covid-19 testing, pandemic relief payments for providers, and revising PAMA regulations for setting Medicare CLFS rates. Other issues included potential FDA regulation of laboratory-developed tests, surprise medical billing, and allergy testing access, according to lobbying disclosure reports.

Lab Industry Lobby Spending

Organizations	2020	2019	2018	2017	2016	2015	2014	2013
ACLA	\$1,766,906	\$1,251,843	\$1,168,193	\$789,227	\$821,476	\$747,730	\$1,236,220	\$940,292
Labcorp	1,750,000	1,650,000	1,390,000	640,000	510,000	425,000	715,000	340,000
Quest Diagnostics	880,000	890,000	1,850,000	1,100,000	1,010,000	770,000	600,000	670,000
College of American Pathologists (CAP)	784,063	1,190,890	1,300,049	1,287,467	1,143,942	1,484,238	1,446,234	1,217,833
Myriad Genetics	716,000	910,000	640,000	770,000	820,000	600,000	650,000	530,000
Coalition for 21st Century Medicine (C21)	498,500	520,000	620,000	640,000	790,000	850,000	840,000	830,000
Exact Sciences	426,000	270,000	340,000	320,000	360,000	270,000	140,000	110,000
Association for Molecular Pathology	230,000	250,000	240,000	240,000	240,000	200,000	190,000	120,000
Opko/BioReference	210,000	175,000	165,000	180,000	120,000	120,000	180,000	40,000
Amer. Society for Clinical Pathology (ASCP)	138,500	168,625	208,675	202,175	240,250	217,000	185,950	184,000
Total, 10 organizations	\$7,399,969	\$7,276,358	\$7,921,917	\$6,168,869	\$6,055,668	\$5,683,968	\$6,183,404	\$4,982,125

Source: Center for Responsive Politics

Public Lab CEOs Paid Average \$14 Million In 2020

The top executives at 25 publicly traded lab companies were paid an average of \$14 million each last year, according to an analysis of shareholder proxy statements by *Laboratory Economics*. Altogether, the 25 CEOs earned a total of \$353 million, including a whopping \$322 million from stock and option awards.

The highest paid executives were at **Guardant Health** (Redwood City, CA). The company awarded its co-founders **Helmy Eltoukhy, PhD**, 42, Chief Executive, and **AmirAli Talasaz, PhD**, 41, Chairman & President, massive long-term restricted stock unit awards worth \$114 million each in 2020. In conjunction with these awards, they each agreed to forgo any base salary, annual bonuses or time-based long-term incentives for seven years effective June 1, 2021. Guardant Health, which markets liquid-biopsy tests under the brand name Guardant360, recorded a net loss of \$254 million for the year ended December 31, 2020, as compared to a net loss of \$76 million for the previous year; revenue increased by 34% to \$287 million.

The next highest paid executive was **Kevin Conroy**, 55, Chairman and CEO of **Exact Sciences** (Madison, WI). Conroy received total compensation of \$20.1 million, including salary of \$498,976, stock and option awards of \$18.2 million, bonus of \$1.4 million and other compensation of \$45,731. Exact recorded a net loss of \$849 million in 2020 versus a net loss of \$84 million for the previous year; revenue increased by 70% to \$1.491 billion.

Labcorp's Adam Schechter, 56, President & CEO, earned total compensation of \$14.7 million, and **Quest Diagnostics' Stephen Rusckowski**, 63, Chairman & CEO, earned \$14.1 million.

Meanwhile, the lowest-paid public-lab CEO last year was **Ming Hsieh**, 65, Chairman and CEO of **Fulgent Genetics** (Temple City, CA), which focuses on low-cost genetic testing. Hsieh received total compensation of \$248,000, including a salary of \$240,000 and bonus of \$8,000.

\$56K Median Lab Employee Compensation

Separately, data from five of the largest publicly traded lab companies shows they paid their combined 125,149 employees a median average of approximately \$55,614 each in 2020. Exact Sciences had the highest median employee compensation of \$110,616, followed by NeoGenomics at \$76,844, and Quest Diagnostics at \$71,645. Median employee compensation at Opko Health, including BioReference Labs, was \$42,848 and Labcorp's median was \$41,670. Over the past three years (2017-2020), median compensation of employees at the five big publicly traded lab companies has grown by 6.2% per year.

Median Employee Compensation at Five Big Labs

Company	Employees (FTEs)*	2020	2019	2018	2017	3-Yr CAGR
Labcorp (Diagnostics & Drug Development)	68,780	\$41,670	\$41,834	\$43,230	\$41,609	0.0%
Quest Diagnostics	44,500	71,645	53,492	46,749	48,194	14.1%
Opko Health (Diagnostics & Drug Development)	5,269	42,848	41,445	38,661	38,661	3.5%
Exact Sciences	4,900	110,616	113,869	98,783	98,724	3.9%
NeoGenomics	1,700	76,844	74,903	70,258	69,825	3.2%
Totals & Weighted Median Average	125,149	\$55,614	\$49,282	\$46,879	\$46,494	6.2%

*Part-time employees were counted as ½ FTE.

Source: *Laboratory Economics* from company proxy statements

2020 Public Laboratory CEO Compensation

Company/Executive	Salary	Value of Stock & Option Awards	Bonus & Incentives	Comp*	Total Compensation
Aspira Women's Health					
Valerie Palmieri, 59, President & CEO	\$400,000	\$351,800	\$200,000	\$682	\$952,482
Biocept					
Michael Nall, 58, President & CEO	495,000	1,043,830	235,125	9,450	1,783,405
Biodesix					
Scott Hutton, 49, President & CEO	364,175	1,051,652	167,636	71	1,583,534
CareDx Inc.					
Peter Maag, PhD, 54, Executive Chmn. & former CEO	488,700	5,049,535	860,220	1,560	6,400,015
Castle Biosciences					
Derek J. Maetzold, 59, President & CEO	550,000	4,325,639	457,600	11,400	5,344,639
DermTech Inc.					
John Dobak, MD, 55, Chief Executive Officer	480,000	2,796,524	187,200	557	3,464,281
Enzo BioChem					
Elazar Rabbani, PhD, 77, Chairman & CEO	611,000	182,140	500,000	194,661	1,487,801
Exact Sciences					
Kevin Conroy, 55, Chairman & CEO	498,976	18,202,096	1,374,450	45,731	20,121,253
Exagen					
Fortunato Ron Rocca, 59, President & CEO	499,733	1,742,603	566,799	8,550	2,817,685
Fulgent Genetics					
Ming Hsieh, 65, Chairman & CEO	240,000	0	8,000	0	248,000
Guardant Health					
AmirAli Talasaz, PhD, 41, Chairman & President	209,937	113,595,323	0	79,780	113,885,040
Helmy Eltoukhy, PhD, 42, Chief Executive	209,937	113,595,323	0	65,726	113,870,986
Interpace Diagnostics					
Jack Stover, 67, President & CEO	453,622	417,951	45,000	848,603	1,765,176
Invitae					
Sean George, PhD, 47, President & CEO	451,346	3,430,020	0	0	3,881,366
Labcorp					
Adam Schechter, 56, President & CEO	1,250,000	9,864,802	3,187,500	433,259	14,735,561
Mark Schroeder, 60, Executive VP, President Diagnostics Lab Operations	505,000	1,576,083	850,000	61,497	2,992,580
Myriad Genetics					
Paul Diaz, 59, President & CEO	382,663	13,894,634	682,000	541,524	15,500,821
Natera Inc.					
Steve Chapman, 42, President & CEO	486,732	7,291,047	296,884	8,550	8,083,213
NeoGenomics					
Douglas VanOort, 65, Chairman & CEO	669,039	3,000,000	450,000	3,000	4,122,039
Opko Health Inc.					
Phillip Frost, MD, 84, Chairman & CEO	960,000	567,000	0	11,200	1,538,200
Jon Cohen, MD, 67, Exec. Chmn., BioReference Labs	575,000	1,755,000	1,150,000	11,200	3,491,200
Progenity					
Harry Stylli, PhD, 59, Chairman & CEO	395,000	5,354,503	0	3,819	5,753,322
Psychemedics					
Raymond Kubacki, Jr., 76, Chairman & CEO	509,654	159,401	0	16,146	685,201
Quest Diagnostics					
Stephen Rusckowski, 63, Chairman & CEO	1,107,692	9,779,903	3,000,000	194,013	14,081,608
Veracyte Inc.					
Bonnie Anderson, 63, Chairman & CEO	625,000	3,319,345	625,000	2,000	4,571,345
Totals, 25 executives	\$13,418,206	\$322,346,154	\$14,843,414	\$2,552,979	\$353,160,753
Averages, 25 executives	\$536,728	\$12,893,846	\$593,737	\$102,119	\$14,126,430

*Other compensation includes reimbursement for financial planning services, car allowance, personal liability insurance premiums, executive physical exams, home security systems, country club memberships, personal use of company jets and other perks.

Source: *Laboratory Economics* from company proxy statements

Lab Stocks Up 14% Year To Date

Twenty-two lab stocks have risen by an unweighted average of 14% year to date through June 11. In comparison, the S&P 500 Index is up 13% thus far in 2021. The top-performing lab stocks so far have been Interpace Biosciences, up 223%; Psychomedics, up 62%; and Myriad Genetics, up 50%. Shares of Labcorp are up 27%, while Quest Diagnostics is up 7% year to date.

Company (ticker)	Stock Price 6/11/21	Stock Price 12/31/20	2021 Price Change	Enterprise Value (\$ mill)	Enterprise Value/Revenue	Enterprise Value/EBITDA
Labcorp (LH)	\$258.55	\$203.55	27%	\$29,730	1.9	6.8
Exact Sciences (EXAS)	121.89	132.49	-8%	21,900	14.2	NA
Sonic Healthcare (SHL.AX)*	35.60	32.15	11%	19,780	2.5	9.7
Quest Diagnostics (DGX)	127.29	119.17	7%	19,010	1.8	6.5
Guardant Health (GH)	120.94	128.88	-6%	11,590	38.9	NA
Natera (NTRA)	103.88	99.52	4%	9,020	20.1	NA
Invitae (NVTA)	31.22	41.81	-25%	6,110	19.2	NA
NeoGenomics (NEO)	43.10	53.84	-20%	4,860	10.7	341.6
CareDx (CDNA)	91.25	72.45	26%	4,400	19.9	NA
Opko Health (OPK)	3.72	3.95	-6%	2,810	1.6	11.5
Myriad Genetics (MYGN)	29.73	19.77	50%	2,330	4.2	NA
Veracyte (VCYT)	36.14	48.94	-26%	2,120	17.3	NA
Castle Biosciences (CSTL)	71.89	67.15	7%	1,380	20.2	NA
DermTech Inc. (DMTK)	40.55	32.44	25%	916	133.6	NA
Aspira Women's Hlth (AWH)	5.87	6.71	-13%	613	124.4	NA
Biodesix (BDSX)	15.13	20.16	-37%	386	5.6	NA
Progenity (PROG)	3.21	5.31	-40%	291	3.6	NA
Exagen (XGN)	14.98	13.20	13%	170	4.0	NA
Enzo Biochem (ENZ)	3.08	2.52	22%	135	1.4	NA
Interpace Biosciences (IDXG)	10.15	3.14	223%	95	2.9	NA
Biocept (BIOC)	4.61	4.44	4%	59	1.4	NA
Psychomedics (PMD)	8.25	5.09	62%	48	2.5	NA
Unweighted Averages			14%	\$137,753	20.5	75.2

*Sonic Healthcare's figures are in Australian dollars

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

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