



*Competitive Market Analysis For Laboratory Management Decision Makers*

**National School Testing Contract Awards Delayed**

Contract awards for managing coordination hubs nationwide for the Department of Health and Human Services (HHS) school testing program have been delayed. The initial schedule called for the testing hub managers in four regions to be announced on April 27. This timetable was pushed back to May 13, but no award announcements had been made as of May 17.

HHS had hoped that each of four regional testing managers would begin overseeing some 1.5 million Covid-19 tests per week for children at schools (K-8th grade) and at homeless shelters by the end of April. The delay means that testing under this program is not likely to be meaningful until the start of the next school year in late August/early September.

The plan was originally developed by Trump testing czar Brett Giroir, MD, and his concept papers were handed off to the incoming Biden administration.

Each regional testing manager will have the responsibilities of coordinating with states, counties and local school districts on testing efforts for K-8 students within their region and ensure proper testing at contracted laboratories. The task of the regional testing managers will be difficult because schools are not required to participate in the program. More details in the April 2021 issue of *Laboratory Economics*.

**Caris Life Sciences Raises Record-Breaking \$830 Million**

Caris Life Sciences (Irving, TX) has raised \$830 million from a group of private equity investors led by Sixth Street Partners (San Francisco, CA). This represents the largest-ever private capital raise for a genetic testing lab company. Caris has now raised a total of \$1.3 billion since 2018 and has a valuation of \$7.83 billion. Caris, which has 1,300 employees and recorded \$165 million of revenue in 2020, will use the money to further commercialize its tumor profiling and blood-based cancer tests. *More details on page 6.*

**PathNet Aims To Bring Digital Pathology & AI To Independent Pathology Groups**

A new pathology lab startup named PathNet Inc. (Little Rock, AR) has contracted to provide slide preparation, digital scanning and artificial intelligence tools to four independent pathology groups around the country. PathNet, which was founded by pathologist Matthew Leavitt, MD, in August 2020, currently provides technical services to Connect Pathology (Lehi, UT), MDpath (Royal Oak, MI), StarPath (Long Island, NY) and TruCore Pathology (Little Rock, AR). *Continued on page 2.*

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### **PathNet Aims To Bring Digital Pathology & AI** *(cont'd from page 1)*

Leavitt is also founder of Lumea (Lehi, UT), which has developed a biopsy specimen collection device (BxBoard and BxChip). Lumea's BxBoard, which holds six cores in one device, fixes specimens on a flat surface, maximizing surface area on the slide and reducing fragmentation. The BxChip enables pathologists to view 18 cores on one slide while maintaining tissue orientation. Lumea has also developed workflow systems that integrate slide prep, scanning and application of AI algorithms.

PathNet utilizes Lumea's BxChip and digital pathology system to serve its contracted pathology groups. In addition, PathNet uses pathology AI programs developed by Deep Bio Inc. (South Korea).

Hillel Kahane, MD, co-founder of StarPath, helped form the PathNet network to which StarPath belongs. Kahane and fellow StarPath co-founder Todd Randolph, MD oversee the day-to-day operations of their pathology practice as they manage sales staff and continue to perform professional interpretations. As a PathNet member, StarPath is provided with the technical slide prep and digitization using Leica (Aperio) scanners through the PathNet network. Patient specimens are shipped directly to PathNet's technical labs in either Lehi, Utah (located just south of Salt Lake City) or Little Rock, Arkansas. Slide images are made available within 24 hours to Drs. Kahane and Randolph for professional interpretation on their iPad Pros. In addition to the technical labs, PathNet also provides management support such as billing and collections, accounting services, legal services, and other business services to StarPath and other PathNet members.

### **PathNet Contracted Labs**

<i>Pathology Group</i>	<i>Specialty</i>	<i>Key Pathologists</i>
Connect Pathology (Lehi, UT)	general pathology	Jared Szymanski, DO Anthony Perry, MD
MDpath (Royal Oak, MI)	prostate biopsies	Kirk J. Wojno, MD
StarPath (Long Island, NY)	prostate biopsies	Hillel Kahane, MD Todd Randolph, MD
TruCore Pathology (Little Rock, AR)	prostate biopsies	Adam J. Cole, MD Nicole A Massoll MD Matthew R. Lindberg, MD

Source: PathNet Inc.

Kahane says he will typically read the digital images first and then run Deep Bio's AI-powered algorithms to double-check his interpretations. The program generates automatic cancer detection, colored overlays of Gleason scoring, and tumor quantification, and sometimes reveals small areas of concern that might otherwise have been missed by human eye alone, according to Kahane.

### **A simplified workflow for using digital pathology combined with AI follows:**

- A pathologist will view the prostate needle biopsies in the BxChip using their iPad Pro.
- As they come across a focus or foci of prostate cancer, they will annotate those area with a stylus pen and then assign that area a Gleason Score.
- Once they have completed their review of all of the cores, the pathologist can turn on the AI algorithm and see what it highlights as being suspicious for cancer and compare this to what they annotated themselves a few moments earlier.

"This tool is very helpful for quality assurance in that it enables the pathologist to re-look at areas that they did not annotate originally, but that the AI algorithm did, and determine if there are additional areas of interest that require their attention," says Kahane.

## Top 25 Prostate Biopsy Laboratories

LabCorp's Dianon Systems in Oklahoma City is the biggest prostate biopsy lab in the nation based on Medicare Part B carrier allowed payments for G0416 (surgical pathology for prostate needle biopsy). It processed 4,230 allowed Part B services and received \$1.5 million of Medicare-allowed payments for G0416 in 2018.

Inform Diagnostics (Irving, TX), with \$817,758 in Part B allowed payments, and P4 Diagnostix (Beltsville, MD), \$750,794, round out the top three.

There are 11 in-office-based pathology labs among the top 25 prostate biopsy labs. The largest is Advanced Urology Institute (Oxford, FL) with \$609,471 of Part B allowed payments for G0416 in 2018.

StarPath's Kahane notes that the wave of new in-office pathology labs at urology groups leveled off after Medicare introduced the G0416 bundled code for prostate biopsies (irrespective of the number of cores examined) in 2013. The coding change reduced pathology lab reimbursement for the traditional 12-core prostate biopsy exam by roughly 50%. Kahane says some smaller urology groups are now thinking about dismantling their in-office pathology labs and converting the space to exam rooms or offices.

### Top 25 Prostate Biopsy Laboratories by Medicare Part B Allowed Payments for 2018

Organization	Location	Volume of G0416 Services	Average Medicare Allowed Amount	Total Medicare Allowed Payment
LabCorp/Dianon Systems	Oklahoma City, OK	4,230	\$343.26	\$1,451,991
Inform Diagnostics	Irving, TX	2,042	400.47	817,758
P4 Diagnostix/Theranostix	Beltsville, MD	2,425	309.61	750,794
Advanced Urology Institute/Nicholas Maruniak, MD	Oxford, FL	1,446	421.49	609,471
PathMD Labs	Los Angeles, CA	1,241	483.91	600,527
Avero Diagnostics/Tanner Mattison, MD	Irving, TX	1,610	372.99	600,511
Poplar Healthcare/Changhyun Choi, MD	Memphis, TN	1,346	386.12	519,723
Poplar Healthcare/Karla Perrizo, MD	Memphis, TN	1,286	364.63	468,918
LabCorp/Dianon Systems	Shelton, CT	1,165	371.08	432,302
Chesapeake Urology/Hillary Epstein, MD	Towson, MD	815	498.38	406,177
Bio-Reference Laboratories	Elmwood Park, NJ	803	463.74	372,382
University of Mississippi Medical Center/Frank Torres, MD	Jackson, MS	745	493.37	367,559
Urological Surgeons of Long Island/Michael Nagar, MD	Garden City, NY	703	506.07	355,767
Integrated Medical Professionals/C. Friedman, MD, PhD	New York, NY	699	506.07	353,743
Academic Urology/Harvey Bellin, MD	King of Prussia, PA	769	454.56	349,556
Chesapeake Urology/Tehmina Ali, MD	Beltsville, MD	679	496.91	337,400
Urology of Virginia/Jefferson Lin, MD	Virginia Beach, VA	769	428.31	329,367
DCL Pathology/Boniface Ndah, MD	Indianapolis, IN	763	407.68	311,060
Arkansas Urology/Adam Cole, MD	Little Rock, AR	775	385.55	298,798
Incyte Pathology	Spokane Valley, WA	679	436.65	296,487
Comprehensive Urology/Kirk Wojno, MD	Royal Oak, MI	655	425.70	278,836
Michigan Institute of Urology/Rima Tinawi-Aljundi, MD	St. Clair Shores, MI	642	433.83	278,519
Poplar Healthcare/Richard Kinsey, MD	Memphis, TN	1,248	222.89	278,172
UroPartners/Lester Raff, MD	Westchester, IL	611	449.45	274,614
Inform Diagnostics	Union, NJ	788	343.76	270,884
<b>Total for Top 25 Prostate Biopsy Labs</b>		28,934	\$394.39	\$11,411,318
<b>Total for all Medicare Part B Allowed Payments for G0416</b>		150,350	\$297.69	\$44,757,756

\*Based on Medicare Part B Allowed Payments for G0416 in 2018

Source: *Laboratory Economics* from Medicare Provider Utilization and Payment Data for 2018

## Federal Judge Dismisses ACLA's PAMA Lawsuit

Judge Amy Berman Jackson of the District of Columbia District Court has ruled that the American Clinical Laboratory Assn.'s PAMA lawsuit is moot and dismissed the case. ACLA now has 60 days to file a notice of appeal challenging the district court's decision. The district court entered its judgment on March 30, so any potential appeal must be filed by May 29, 2021.

ACLA originally filed the lawsuit in December 2017 against then HHS Secretary Alex Azar (who has since been replaced by Xavier Becerra). ACLA contends that HHS wrongly excluded hospital outreach labs from the first private-payer rate survey used to calculate Medicare CLFS rates effective in 2018. This led to an over-representation of the low rates offered by independent labs (especially Quest Diagnostics and LabCorp) leading to Medicare CLFS rate cuts that were more severe than they should have been.

However, in November 2018, CMS published a final rule that expanded its definition of "applicable laboratory" to include hospital outreach labs. The rule requires hospitals to gather payment information for their nonpatient outreach tests in first-half 2019 for reporting in early 2020 (now postponed until 2022). This data together with information from independent labs and POLs will be used to determine Medicare CLFS rates starting in 2023.

Judge Jackson ruled that the inclusion of hospital outreach lab payment data for the next survey has made ACLA's lawsuit moot. The only other available remedy would be makeup pay for any past reimbursements that were calculated from the initial flawed private-payer rate survey. But the PAMA law states that "payment amounts under this section shall not be subject to any adjustment." Therefore, Judge Jackson said that the district court "could not order the agency to revise any payment amounts in the fee schedules used to determine 2018–2020 payments or any particular payments to plaintiff's members."

### MedPAC Leans Toward Smaller PAMA Survey of Efficient Labs

On April 1-2, the Medicare Payment Advisory Commission (MedPAC) held its second meeting to explore potential survey methodologies that could be used to collect private payer rates from a sample of labs in order to reduce the burden of reporting.

MedPAC is an independent agency comprised of 17 members appointed by the Comptroller General of the United States. The LAB Act of 2019 mandated MedPAC to analyze less burdensome ways to collect private-payer payment data from labs that result in a representative sample of all lab segments (independents, hospitals and POLs). MedPAC must give a final report to CMS and Congressional committees this June.

At its recent meeting, MedPAC Senior Policy Analyst Brian O'Donnell noted that a third-party contractor, RTI International, examined potential survey methodologies that could be used to collect private payer rates from a representative sample of all labs. RTI found that setting Medicare CLFS rates based on a small representative sample of labs would increase program spending by 10% to 15%, relative to the spending that would result from current CLFS rates.

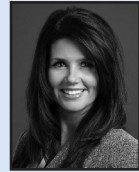
O'Donnell said that for routine tests, policymakers should consider excluding high private-payer rates that are likely related to negotiating leverage, not the cost of furnishing tests. For example, he said that Medicare could set reimbursement based on private-payer rates of relatively efficient labs, instead of all labs.

Another instance in which private payer data might produce suboptimal Medicare payment rates is among new, high-cost tests, such as genetic tests. O'Donnell noted that private payers may have a limited ability to negotiate rates for new, high-cost proprietary tests.

The bottom line is that MedPAC seems to be leaning toward a simplified PAMA rate survey focused on the most efficient (i.e., lower cost) independent labs, hospital outreach labs and POLs. In addition, MedPAC's final report may include recommendations to rein in spending growth for high-priced genetic tests.

## Spotlight Interview with Yosemite Pathology's CEO Jennifer Pinasco

Yosemite Pathology Medical Group (YPMG-Modesto, CA) is one of the largest independent physician-owned pathology practices in Central and Northern California. YPMG serves more than 650 clients, including over 22 hospitals and over 40 ambulatory surgery centers, along with providing several independent clinical laboratory medical directorships throughout the region. YPMG has 170 employees, of which 32 are pathologists, two full-service pathology laboratories (Modesto and Bakersfield), one fine-needle aspiration clinic and six remote professional office locations. Here's a summary of what's happening at YPMG from CEO Jennifer Pinasco.



Jennifer Pinasco

### **Does YPMG have particular areas of specialty?**

All YPMG Pathologists are AP and CP board certified with various sub-specialties in dermatopathology, cytopathology, hematopathology, and a special interest and expertise in breast pathology, thyroid pathology, uropathology and GI.

### **How many Covid-19 tests is YPMG doing per day?**

We are using the Hologic Panther platform and averaging 75 to 100 tests per day, down 60% from our highest volume in 2020. We have a 24-hour turnaround. Our current positivity rate is around 7% and steadily declining, which is to be expected now with vaccinations being administered and herd immunity being realized. Currently, reimbursement from some select payers for Covid testing has been a challenge and thus more of a focus for our RCM department.

### **What is your Covid testing capacity?**

We have two Panthers but were limited in our ability to meet the daily testing demands in 2020 due to the supply allocation restrictions and specialized pipette tip shortage, so we had to keep our maximum at 175 tests per day.

### **Are you offering Covid-19 antibody testing? If yes, how many are you doing?**

We are not currently offering antibody testing, but we haven't really had a huge demand for it in our region either. Our clients are looking more for acute results for their staff, patient consultations and scheduling procedures.

### **Has your laboratory staff been vaccinated against Covid-19?**

Yes, about 50% of our staff have been vaccinated. Understanding it is a personal choice at this point, we continue to offer resources and information about it while maintaining our face-covering policy, since not everyone is vaccinated and until we review new guidance from the CDC.

### **Has your routine testing volume fully recovered from the impact of the pandemic?**

We are beating our Q1 2021 projections, which doesn't include our Covid-19 testing volume. We've seen an interesting shift in our specimen to accession ratio and seeing a slight dip in accessions but an increase in specimens per case, which I think is largely attributable to more procedures being performed at the ambulatory surgery centers and outpatient offices.

### **Are there any particular areas of non-Covid testing that are still depressed?**

Overall, we are seeing the larger hospitals and ambulatory surgery centers ramp up and beat 2019 volumes; however, some of the smaller rural facilities are still working their way there. Staffing and Covid-initiated protocols are some of the challenges they are still managing, but we anticipate that to improve for them over the next several months. Outpatient volume has fully recovered and grown, including women's health. It is reassuring to see people seeking the critical diagnostic and preventative care they need that was postponed due to the pandemic.

### **Are you experiencing any shortages in staffing?**

Right now, our biggest staffing needs are pathologists and pathology technicians to support our growing footprint. We never seem to have enough, but we have two internal recruiters that work on

staffing needs continuously and also partner with external recruiters for specialty positions when needed. We do promote and train from within and have strong internal mentorship programs to encourage those who want to excel or have hit the top of their 'S' curve.

**How did YPMG's volume and revenues fare in 2020 compared to 2019?**

Overall, we had a 4% growth in volume in 2020 over 2019. Covid volume and revenue helped fill in the gaps to end the year revenue-neutral compared to 2019. We saw a 12% increase in revenue from 2017 to 2018 and 7% from 2019 to 2020 and expect to reach our goal of 25% revenue growth in 2021 due to organic growth and our acquisition of Bakersfield Pathology Medical Group in Bakersfield in October of 2020. We ended 2020 handling 175,000 cases and over 300,000 specimens, including Covid tests.

**To what extent are you using digital pathology? Are you using it for primary diagnosis?**

We have two scanners, Aperio AT2 and Nanozoomer, used only for our dermatopathologists for primary diagnosis at our remote locations and occasionally for internal slide consultations within the practice. We certainly see it as a useful tool for case management as we expand. Hopefully, reimbursement will catch up with the investment at some point.

**What are your plans for future growth?**

We've completed six acquisitions since 2012 and have plans to continue to expand in California. It's been very difficult for pathology groups to sustain operations due to the continuous reimbursement cuts over the years, let alone the smaller group practices with limited resources. Combining synergies and expertise, our acquisitions create a stronger level of stability for both groups to withstand economic disruptions in not only pathology but in healthcare in general. We also have an aggressive sales pipeline that is focused on organic growth and expanding our reach in new territories.

In addition, plans are underway this year to bring flow cytometry testing in-house, add additional testing to our Panther platform and finish up our lab expansion. We are also very interested in participating in clinical trials and unique collaborations and partnerships that add value in precision medicine.

Next year, we are looking at bringing FISH testing and NGS in house, along with incorporating AI into our practice.

**Caris Life Sciences Raises Record-Breaking \$830 Million** *(cont'd from page 1)*

Other significant investors in Caris' latest equity round included T. Rowe Price, Silver Lake, Fidelity Management and Coate.

Caris Life Sciences was founded by its Chairman and CEO, David Halbert, in 2008. The company sold its traditional anatomic pathology testing business, Caris Diagnostics (now named Inform Dx), to Miraca Holdings for \$725 million in 2011.

Caris currently focuses on molecular profiling of solid biopsies. Its Caris Molecular Intelligence service analyzes the DNA and RNA for all 22,000 genes to help oncologists personalize cancer patient treatment. In November 2020, Caris received a proprietary laboratory analyses (PLA) code 0211U (Oncology (pan-tumor), DNA and RNA by next-generation sequencing, utilizing formalin-fixed paraffin-embedded tissue), which has a current Medicare rate of \$8,455. Caris plans to use the cash raised to commercialize a new platform to assess liquid biopsies (aka blood samples) using a similar process.

**Caris at a Glance**

Chairman & CEO .....	David Halbert
Vice President .....	Brian Brille
Pres./Chief Sci. Officer.....	David Spetzler, PhD
Total employees.....	1,300
Annual Revenue (2020).....	\$165M
Main CLIA Lab.....	Phoenix, AZ
Current Valuation .....	\$7.83 billion

## Cigna To Stop PC Payments For Clinical Lab Tests

Cigna has announced it will no longer pay for the professional component of clinical pathology (PC/CP) effective July 11, according to an update issued April 12 ([https://static.cigna.com/assets/chcp/secure/pdf/resourceLibrary/clinReimPolsModifiers/Notifications/modifier\\_26\\_professional\\_component.pdf](https://static.cigna.com/assets/chcp/secure/pdf/resourceLibrary/clinReimPolsModifiers/Notifications/modifier_26_professional_component.pdf)). The change will have the greatest impact on hospital-based pathology groups that bill Cigna for professional services they provide to hospital inpatients and outpatients that have received clinical lab tests.

The Cigna policy states that separate PC reimbursement is not appropriate when a hospital owns the lab equipment, purchases the supplies, employs a technologist to perform the tests and employs a physician to interpret the results. These services are all covered in the bundled payments made for inpatient and outpatient services.

However, pathologists will still be able to bill Cigna for the professional component of anatomic pathology services.

Cigna's new PC/CP policy should come as no surprise, as other major health insurers, including UnitedHealthcare, Humana and Aetna, have made similar changes over the past 10 years, according to Mick Raich, President of RCM Services at Lighthouse Lab Services/Vachette Pathology.

Raich notes that there are several states where Blue Cross/Blue Shield and/or Medicaid plans still pay PC/CP, but probably not for too much longer. He says that pathology groups located in these states, like California, Florida, Illinois and Texas, should be working on a strategy to offset the future loss of PC/CP revenue. These payments can comprise as much as 30% of the overall revenue at some hospital-based pathology groups.

Raich says the Cigna change should trigger pathology groups to review their current contracts. Ideally, he says that groups should negotiate new contracts that raise their anatomic pathology rates from Cigna to offset the loss of PC/CP payments. Alternatively, hospital-based groups can seek higher Part A/Medical Director contract fees to offset the loss, advises Raich.

## United Makes Covid Testing Payment Difficult For Out-Of-Network Labs

The CARES Act requires health insurers to pay labs, both in-network and out-of-network, for Covid-19 testing at no cost to the patient. However, some insurers seem to be stonewalling labs, with some labs still waiting to get paid for Covid-19 PCR tests they performed over one year ago.

UnitedHealthcare is making it especially difficult for out-of-network labs to get paid, notes Ann Lambrix, Vice President of RCM Consulting at Lighthouse Lab Services/Vachette Pathology. Lambrix says that UHC is not explicitly denying claims, but rather demanding that out-of-network labs supply patient medical records, not responding to lab questions, and sitting on unpaid claims. For the most part, out-of-network labs have been reasonable in what they are billing insurers for Covid-19 PCR tests—in the range of approximately \$125, according to Lambrix.

Lambrix notes that some out-of-network labs have grown so frustrated with non-payment from UHC that they filed a complaint with the Department of Insurance in Alabama. "This was a last resort, but it has gotten the lines of communication open between labs and UHC," she adds.

### AHIP Alleges Price Gauging by Out-of-Network Labs

Meanwhile, America's Health Insurance Plans (AHIP), the trade organization for health insurers,

says that out-of-network labs are taking advantage of CARES Act regulations that require insurers to pay the fully billed charge for Covid testing to out-of-network labs.

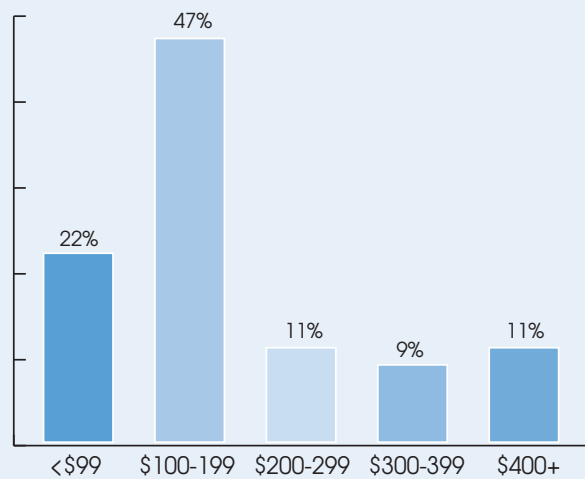
AHIP conducted a survey of its commercial health plan members in late 2020 that showed that almost a quarter (23%) of all claims for Covid-19 tests were from out-of-network labs. The survey found that the average Covid-19 PCR test from an out-of-network lab cost \$185 versus \$130 for in-network labs. Twelve percent of out-of-network claims for Covid-19 PCR tests were priced at more than \$390, according to the AHIP survey.

“Congress should eliminate the ability for price gouging to occur by setting a reasonable market-based pricing benchmark for tests delivered out of network,” says AHIP.

### Kaiser Survey Finds Hospital Covid Test Rates as High as \$1,419

Separately, Kaiser Family Foundation (KFF) analyzed Covid test pricing at 93 of the nation’s largest hospitals in late April. They found that these hospitals had out-of-network prices for Covid-19 diagnostic tests (PCR and antigen) that ranged between \$20 and \$1,419 with a median of \$148 per test, not including the price of a provider visit, facility fee, or specimen collection. The KFF survey found that 22% of test charges were below \$100, nearly half (47%) were priced between \$100 and \$199, and 31% were priced at \$200 or above.

### Prices for Out-of-Network Covid-19 Diagnostic Tests at Large Hospitals



Source: KFF analysis of Covid-19 diagnostic test prices from the public websites of 93 large hospitals, April 2021 (<https://www.healthsystemtracker.org/brief/covid-19-test-prices-and-payment-policy/>)

## JAMA Study Details High Cost Of Out-Of-Network Lab Tests

Private insurers pay out-of-network labs more than double the contracted rates paid to in-network labs for the same lab tests, according to a study published in JAMA Internal Medicine (published online April 26, 2021). The study also found that out-of-pocket spending by patients (eg, copayment) was \$25 higher for an average out-of-network lab test than an in-network lab test. In addition, patients who got an out-of-network lab test incurred an average balance bill of \$81.

The study’s lead author was Aditi P. Sen, PhD, a health economist and assistant professor in the Department of Health Policy and Management at the Johns Hopkins Bloomberg School of Public Health. He examined claims data from the Truven Marketscan Commercial claims database for 2018.

Thirteen million enrollees (average age 42) in self-insured HMO, PPO, EPO and consumer-driven health plans and high-deductible health plans were analyzed. Thirty-percent (3.95 million) of individuals had at least one outpatient lab test performed by an independent lab, POL, hospital outpatient lab, or other lab in 2018, of whom 5.9% (230,859) had an out-of-network lab test. Individuals in the sample had a total of 36.84 million lab tests in 2018, of which 90% (33.25 million) were performed by an independent lab, 7% (2.5 million) by a POL, 2% (572,755) by a hospital outpatient lab, and 1% (520,221) in other settings.

Among specific common lab tests, the study found, for example, that private insurers paid an aver-



age of \$11.31 for lipid panels performed by in-network labs versus \$29.77 paid to out-of-network labs. The total out-of-pocket cost to a patient having a lipid panel performed by an in-network lab averaged \$3.14, while the same test performed by an out-of-network lab cost the patient a total of \$88.14, including an average copay of \$19.32 plus balance bill of \$68.77.

The study noted that outpatient lab tests represent the biggest and fastest-growing out-of-network spending category—most other categories are decreasing. For example, the study calculated that out-of-network outpatient lab tests were five times more common than out-of-network emergency department visits and 34 times more common than out-of-network anesthesiology services. “Recent legislation [The No Surprises Act] protects patients against surprise bills starting in 2022; federal rulemaking should ensure that laboratory testing is covered under this law,” according to study author Sen.

### In-Network vs. Out-of-Network for Common Lab Tests in 2018

Lab Test (CPT code)	In-Network Avg. Allowed Amount	Out-of-Network Avg. Allowed Amount	Percent Difference
Lipid Panel (80061)	\$11.31	\$29.77	163%
Venipuncture (36415)	2.89	3.57	24%
Comprehensive Metabolic Panel (80053)	9.77	24.58	152%
Complete Blood Cell Count (85025)	7.50	15.01	100%
Glycated Hemoglobin (83036)	9.32	22.77	144%
Drug Screening Tests-Presumptive (80307)	80.65	342.74	325%
Surgical Pathology (88305)	104.14	139.05	34%
General Health Panel (80050)	28.30	67.03	137%
Vitamin D Test (82306)	26.71	73.29	174%

Source: Frequency and Costs of Out-of-Network Bills for Outpatient Laboratory Services Among Privately Insured Patients (*JAMA Internal Med.* Published online April 26, 2021)

## NeoGenomics To Buy Liquid-Biopsy Firm Inivata

NeoGenomics has agreed to acquire the 80% of U.K.-based liquid biopsy company Inivata that it does not already own for \$390 million. NeoGenomics originally acquired a nearly 20% stake in Inivata for \$25 million in May 2020.

Inivata has 90 employees at an R&D facility in Cambridge, England, and a CAP-accredited laboratory in Research Triangle Park, North Carolina.

NeoGenomics has been marketing Inivata’s InVisionFirst-Lung liquid biopsy test in the United States since mid of last year. InVisionFirst is a 37-gene profiling test panel for detecting oncogenic driver mutations and therapy targets for patients with advanced non-small cell lung cancer (NSCLC). The test received a local coverage determination for Medicare reimbursement from Palmetto GBA in 2019, and is currently reimbursed at \$3,500 per test (CPT 81479).

Inivata is also developing a second liquid biopsy assay, RaDaR, for the detection of minimal residual disease (MRD) and early detection of relapse in patients with a variety of different cancers, including NSCLC, head and neck cancer and early-stage breast cancer. Inivata expects to submit data for RADaR through the MoIDx pathway for reimbursement around the turn of the year, which should allow for commercialization as a laboratory-developed test starting in mid-2022.

## Myriad Genetics Seeks Turnaround Through Divestitures

**M**yrriad Genetics (Salt Lake City, UT), which has been hurt by competition in its flagship BRACAnalysis testing market and a slowdown in testing demand related to pandemic shut-downs, has announced plans to sell several of its smaller testing labs.

### LabCorp To Buy Myriad's Vectra Testing Business

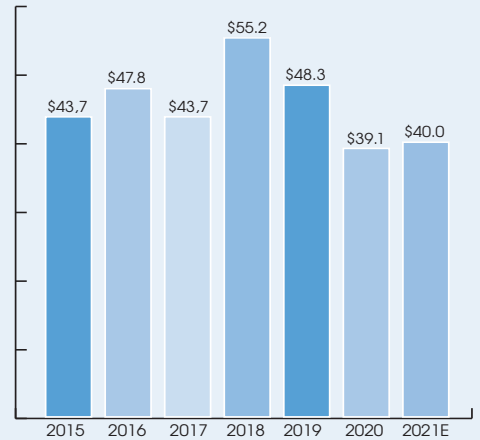
LabCorp has agreed to buy Myriad Genetics' autoimmune testing business, including the Vectra rheumatoid arthritis (RA) test, for \$150 million in cash. The deal is expected to be finalized by Sept. 30. Myriad originally added the Vectra test through its acquisition of Crescendo Biosciences (South San Francisco) for \$259 million in February 2014.

Myriad's Vectra test is a proprietary laboratory-developed blood test that analyzes 12 biomarkers (Interleukin-6, Epidermal Growth Factor, CRP, etc.) to measure RA disease activity. The concentrations of these 12 biomarkers are combined with age, gender and adiposity (i.e., leptin) information, to generate a single score on a scale of 1 to 100. Rheumatologists use the test score to monitor how well a patient's treatment plan is controlling inflammation.

The Vectra test is reimbursed by the Medicare CLFS through CPT code 81490 at a current rate of \$840.65. During the three-year period 2016-2019, the volume of Medicare Part B allowed services for CPT 81490 declined from 49,713 tests to 36,929 tests, or -9.4% per year. Myriad reported total revenue of \$39.1 million for its Vectra testing business for the 12 months ended June 30, 2020. *LE* projects the business will generate roughly \$40 million of revenue for the fiscal year ending June 30, 2021.

LabCorp says that a meaningful portion of Vectra test specimens currently flow through LabCorp PSCs and clients to Myriad's autoimmune testing lab in South San Francisco.

Annual Revenue for Myriad's Vectra Testing Business (\$ millions)



Source: Myriad Genetics and *LE* estimate for 2021

### Castle To Acquire Myriad's Melanoma Testing Laboratory

Castle Biosciences (Friendswood, TX) has agreed to buy Myriad myPath Laboratory from Myriad Genetics for \$32.5 million in cash. Myriad myPath Laboratory is a CLIA-certified laboratory in Salt Lake City, where the myPath Melanoma 23-gene expression profile (GEP) test is performed. Upon closing, expected by June 30, Castle will be the sole provider of the myPath Melanoma test.

The myPath Melanoma test is a gene-expression-based profile that is performed on biopsy tissue to aid dermatopathologists in diagnosing indeterminate skin lesions. The test has been given a proprietary laboratory analysis (PLA) code (CPT 0090U) and is reimbursed by Medicare at \$1,755. Estimated annual revenue for Myriad's myPath Laboratory is less than \$10 million per year.

Castle anticipates that the myPath Melanoma test will complement its existing skin cancer tests. For example, Castle's DecisionDX-Melanoma test, which has a Medicare reimbursement rate of \$7,193, is designed to identify the risk of recurrence or metastasis in Stage I, II, and III melanoma based on the profile of 31 genes within a patient's tumor tissue.

### Still Looking for Buyer of Rules Based Medicine

Finally, Myriad says that it is also pursuing the sale of Myriad RBM, which provides contract research services for the pharmaceutical industry. Myriad originally acquired Rules Based Medicine (RBM) for \$80 million in 2011. Myriad RBM has annual revenue of approximately \$36 million.

## Pathologist Compensation Held Steady Despite Pandemic Shutdowns

Defying predictions, pathologist compensation only fell slightly last year—to an average of \$316,000 in 2020 from \$318,000 in 2019, according to the findings of the 2021 Medscape Physician Compensation Report.

Overall, physician salaries were stable in 2020. The Medscape survey found that average salaries for primary care physicians held steady at \$242,000 from \$243,000 the previous year. Similarly, specialists' average salaries fell by only \$2,000 to \$344,000.

About 44% of all surveyed physicians reported reductions in patient volume and nearly one in four saw a decrease in hours. However, the combination of government pandemic relief programs, staff reductions, capitation plans which continued to pay physicians, and reimbursement for telemedicine visits blunted the impact, according to Medscape.

Plastic surgeons had the highest overall average compensation last year at \$526,000, followed by orthopedic surgeons (\$511,000) and cardiologists (\$459,000).

The Medscape survey collected responses between October 2020 and February 2021 from 17,903 physicians across 29 specialties. Surveyed doctors reported their compensation for patient care including salary, bonus and profit-sharing contributions. Approximately 358 pathologists, comprising 2% of total survey respondents, participated.

### Pathologists Near the Top for Paperwork

Medscape asked physicians their estimated hours per week spent on paperwork and administration. Infectious disease doctors spent the most time on paperwork at 24.2 hours per week, followed by public health (20.7 hours) and nephrology (19.8 hours). Pathologists ranked fifth highest with 19 hours. Specialists spending the least time on paperwork included anesthesiology (10.1 hours), ophthalmology (10.3 hours) and radiology (11.6 hours).

### Would You Choose the Same Specialty Again?

Ninety-six percent of surveyed dermatologists said they would choose the same specialty again. Pathologists were in the middle with 85% saying they would make the same choice again. At the low end, only 67% of public health doctors said they would choose this specialty again.

### Average Annual Physician Compensation Trends (\$000)

<i>Selected Specialties</i>	<i>2020</i>	<i>2019</i>	<i>2018</i>	<i>2017</i>	<i>2016</i>	<i>2015</i>	<i>5-Year CAGR</i>
Plastic Surgery	\$526	\$479	\$471	\$501	\$440	NA	NA
Orthopedics	\$511	\$511	\$482	\$497	\$489	\$443	2.9%
Cardiology	\$459	\$438	\$430	\$423	\$410	\$410	2.3%
Urology	\$427	\$417	\$408	\$373	\$400	\$367	3.1%
Radiology	\$413	\$427	\$419	\$401	\$396	\$375	2.0%
Gastroenterology	\$406	\$419	\$417	\$408	\$391	\$380	1.3%
Oncology	\$403	\$377	\$359	\$363	\$330	\$329	4.1%
Dermatology	\$394	\$411	\$419	\$392	\$386	\$381	0.7%
Pathology	\$316	\$318	\$308	\$286	\$293	\$266	3.5%
Ob/Gyn	\$312	\$308	\$303	\$300	\$286	\$277	2.4%
Psychiatry	\$275	\$268	\$260	\$273	\$235	\$226	4.0%
Internal Medicine	\$248	\$251	\$243	\$230	\$225	\$222	2.2%
Infectious Disease	\$245	\$246	\$239	\$231	\$228	\$215	2.7%
Public Health	\$237	\$232	\$209	\$199	NA	NA	NA
Pediatrics	\$221	\$232	\$225	\$212	\$202	\$204	1.6%

Source: Medscape Physician Compensation Reports, 2016-2021

## Lab Stocks Up 1% Year To Date

Twenty-two lab stocks have risen by an unweighted average of 1% year to date through May 14. In comparison, the S&P 500 Index is up 11% thus far in 2021. The top-performing lab stocks so far have been Interpace Biosciences, up 155%; Myriad Genetics, up 38%; and LabCorp, up 35%. Shares of Quest Diagnostics are up 14% year to date.

Company (ticker)	Stock Price 5/14/21	Stock Price 12/31/20	2021 Price Change	Enterprise Value (\$ mill)	Enterprise Value/ Revenue	Enterprise Value/ EBITDA
LabCorp (LH)	\$274.50	\$203.55	35%	\$31,440	2.1	7.2
Quest Diagnostics (DGX)	135.42	119.17	14%	20,190	2.0	6.9
Sonic Healthcare (SHL.AX)*	35.36	32.15	10%	19,500	2.5	9.6
Exact Sciences (EXAS)	96.74	132.49	-27%	17,780	11.5	NA
Guardant Health (GH)	112.84	128.88	-12%	10,930	36.7	NA
Natera (NTRA)	93.19	99.52	-6%	7,550	16.8	NA
Invitae (NVTA)	27.74	41.81	-34%	5,220	16.4	NA
NeoGenomics (NEO)	38.11	53.84	-29%	4,380	9.7	307.8
CareDx (CDNA)	66.00	72.45	-9%	2,930	13.2	NA
Opko Health (OPK)	3.70	3.95	-6%	2,440	1.4	10.0
Veracyte (VCYT)	36.56	48.94	-25%	2,150	17.4	NA
Myriad Genetics (MYGN)	27.38	19.77	38%	2,000	3.6	NA
Castle Biosciences (CSTL)	55.17	67.15	-18%	896	13.2	NA
DermTech Inc. (DMTK)	33.59	32.44	4%	779	132.4	NA
Aspira Women's Hlth (AWH)	5.11	6.71	-24%	543	116.7	NA
Biodesix (BDSX)	12.62	20.16	-37%	362	7.9	NA
Exagen (XGN)	12.49	13.20	-5%	224	5.4	NA
Progenity (PROG)	2.36	5.31	-56%	214	2.9	NA
Enzo Biochem (ENZ)	2.98	2.52	18%	126	1.3	NA
Interpace Biosciences (IDXG)	8.00	3.14	155%	86	2.6	NA
Biocept (BIOC)	4.43	4.44	0%	62	2.3	NA
Psychemedics (PMD)	6.70	5.09	32%	42	2.2	NA
Unweighted Averages			1%	\$129,844	19.1	68.3

\*Sonic Healthcare's figures are in Australian dollars

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

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## U.S. Covid-19 Statistics & Analysis

Based on data from CDC, an estimated 44% of the U.S. population had been infected with Covid-19 as of May 16, while 37% has been fully vaccinated. The peak in daily new U.S. confirmed cases came on Jan. 7, 2021.

Separately, *Laboratory Economics* analyzed several factors that may have contributed to variations in Covid deaths per capita among the 50 states and DC. The biggest variation to date has occurred between states with a high median age versus those with low median age.

The 10 oldest states (ME, VT, NH, WV, FL, CT, PA, DE, RI and NJ) have had an average of 1,977 Covid deaths per million of population.

The 10 youngest states (UT, AK, TX, ND, ID, CA, NE, OK, DC and CO) have had an average of 1,566 Covid deaths per million of population.

### U.S. Covid-19 Statistics (as of May 16, 2021)

State	Population	Confirmed Cases	% Population Naturally Infected*	% Population Fully Vaccinated	Covid Deaths	Deaths/1 Million
New Jersey	8,882,190	1,010,490	73%	43%	25,952	2,922
New York	19,453,561	2,133,236	68%	42%	53,200	2,735
Massachusetts	6,892,503	701,490	64%	45%	17,747	2,575
Rhode Island	1,059,361	150,385	64%	45%	2,700	2,549
Mississippi	2,976,149	314,710	61%	26%	7,254	2,437
Arizona	7,278,717	872,496	60%	33%	17,459	2,399
Connecticut	3,565,287	344,977	57%	47%	8,173	2,292
Louisiana	4,648,794	464,833	56%	29%	10,478	2,254
Alabama	4,903,185	537,813	56%	27%	11,038	2,251
South Dakota	884,659	123,645	56%	41%	1,991	2,251
Pennsylvania	12,801,989	1,189,690	52%	38%	26,862	2,098
Indiana	6,732,219	734,736	50%	32%	13,471	2,001
Michigan	9,986,857	976,339	50%	38%	19,790	1,982
North Dakota	762,062	109,057	49%	35%	1,504	1,974
New Mexico	2,096,829	200,650	49%	43%	4,113	1,962
Illinois	12,671,821	1,365,020	49%	36%	24,770	1,955
Georgia	10,617,423	1,115,072	48%	29%	20,505	1,931
Arkansas	3,017,804	338,687	48%	29%	5,793	1,920
Iowa	3,155,070	399,299	48%	40%	6,000	1,902
South Carolina	5,148,714	588,110	47%	31%	9,638	1,872
Tennessee	6,829,174	857,055	45%	29%	12,312	1,803
Nevada	3,080,156	320,539	45%	33%	5,530	1,795
Texas	28,995,881	2,933,558	44%	32%	51,170	1,765
Oklahoma	3,956,971	450,847	43%	32%	6,878	1,738
Kansas	2,913,314	311,705	43%	36%	5,051	1,734
Delaware	973,764	106,873	42%	39%	1,651	1,695
Florida	21,477,737	2,289,522	42%	35%	36,065	1,679
Ohio	11,689,100	1,090,276	42%	37%	19,528	1,671
California	39,512,223	3,768,223	40%	37%	62,659	1,586

State	Population	Confirmed Cases	% Population Naturally Infected*	% Population Fully Vaccinated	Covid Deaths	Deaths/ 1 Million
District of Columbia	705,749	48,530	40%	38%	1,118	1,584
Missouri	6,137,428	592,944	39%	32%	9,514	1,550
West Virginia	1,792,147	158,230	38%	33%	2,757	1,538
Montana	1,068,778	110,644	37%	36%	1,598	1,495
Kentucky	4,467,673	452,250	37%	36%	6,648	1,488
Maryland	6,045,680	455,635	37%	41%	8,925	1,476
Minnesota	5,639,632	593,622	33%	41%	7,364	1,306
Virginia	8,535,519	669,904	32%	39%	11,008	1,290
Wyoming	578,759	59,079	31%	30%	712	1,230
North Carolina	10,488,084	989,338	31%	34%	12,862	1,226
Wisconsin	5,822,434	605,926	30%	41%	6,958	1,195
Nebraska	1,934,408	222,335	29%	39%	2,257	1,167
Idaho	1,787,065	189,908	29%	30%	2,069	1,158
Colorado	5,758,736	531,070	28%	40%	6,562	1,139
New Hampshire	1,359,711	97,563	24%	35%	1,331	979
Washington	7,614,893	424,848	19%	39%	5,684	746
Utah	3,205,958	402,325	18%	29%	2,258	704
Oregon	4,217,737	195,179	15%	38%	2,585	613
Maine	1,344,212	65,523	15%	48%	801	596
Alaska	731,545	66,683	12%	38%	347	474
Vermont	623,989	23,847	10%	45%	252	404
Hawaii	1,415,872	33,637	9%	42%	491	347
10 High Urban Population (NY, NJ, CA, MA, NV, RI, MD, IL, FL, CT)	122,640,519	12,539,517	50%	40%	245,721	2,004
10 Low Urban Population (WY, MT, SD, AK, VT, MS, ME, ND, WV, AR)	13,780,104	1,370,105	42%	37%	23,009	1,670
10 Most Restrictive (CA, DC, VA, VT, MA, HI, ME, WA, CT, NY)	89,663,808	8,214,215	45%	42%	161,133	1,797
10 Least Restrictive (IA, SD, OK, FL, ID, AK, UT, SC, MO, AR)	49,502,951	5,441,970	41%	34%	80,553	1,627
10 Oldest States (ME, VT, NH, WV, FL, CT, PA, DE, RI, NJ)	53,880,387	5,437,100	49%	41%	106,544	1,977
10 Youngest States (UT, AK, TX, ND, ID, CA, NE, OK, DC, CO)	87,350,598	8,722,536	39%	35%	136,822	1,566
<b>Total U.S. Population</b>	<b>328,239,523</b>	<b>32,788,353</b>	<b>44%</b>	<b>37%</b>	<b>583,383</b>	<b>1,777</b>

\*Estimated based on infection fatality rate of 0.4% (i.e., Covid deaths/0.4%=estimated infections)

Source: *Laboratory Economics* from CDC, Worldometers.com and WalletHub.com (for state restriction levels)