

# LABORATORY ECONOMICS

*Competitive Market Analysis For Laboratory Management Decision Makers*

## Labcorp Signs Mega-Deal With Ascension

Labcorp has signed a long-term contract to manage Ascension’s hospital-based labs in 10 states, and will pay \$400 million to acquire certain assets of the St. Louis-based system’s outreach lab business. The transaction is expected to close in the first half of 2022.

Labcorp expects to generate first-year revenue of between \$550 million and \$600 million from the combined hospital lab management business and lab outreach acquisition. The transaction is expected to be accretive to Labcorp’s earnings and cash flow in the first year and is expected to return its cost of capital by year two.

The Labcorp-Ascension deal appears to be primarily focused on clinical lab testing. However, Labcorp CEO Adam Schechter said, “We’re going to explore clinical trial work together and oncology opportunities that enhance patient access.”

*Continued on page 8.*

## UnitedHealthcare Rolls Out Tiered Benefit Design That Promotes Lower-Cost Labs

UnitedHealthcare (UHC) has launched its controversial Designated Diagnostic Provider (DDP) tiered benefit design effective January 1, 2022, in 21 approved states, for its fully insured commercial members.

The rollout will expand to more states pending state insurance department approvals. UHC members who have this benefit and receive non-bundled outpatient lab testing or pathology services from a DDP lab will have lower out-of-pocket costs compared to using non-DDP labs.

The new DDP program is aimed at motivating UHC members to use lower-cost national and regional independent labs versus higher-cost hospital outpatient labs. However, the College of American Pathologists (CAP) is urging UHC to permanently end this program because it pits a patient’s short-term financial interest against their treating physicians’ professional judgment when selecting a pathologist or laboratory.

*Full details on page 2.*

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### UnitedHealthcare Rolls Out New Lab Benefit Design *(cont'd from page 1)*

UHC's current DDP benefit design represents a delayed and scaled back version of initial plans announced a year ago (see *LE*, February 2021). The initial benefit design would have denied any outpatient lab test or pathology service performed by a non-Designated Diagnostic Provider, whether in-network or out-of-network. These claims would have been denied as "non-covered" and members would have been responsible for payment. This version of the DDP program was initially scheduled to begin on July 1, 2021, but was postponed and redesigned.

The new version of UHC's DDP benefit design shifts the financial incentive to use a DDP lab or pathologist more toward the member. Labs with the DDP designation have lower fee schedules,

*UHC's DDP network represents a distinct tier of accredited in-network labs with lower costs.*

especially when compared to non-DDP hospital-based labs. As a result, UHC members that use a lab that has the DDP designation will have lower out-of-pocket expenses when meeting deductibles.

UHC spokesperson Tracey Lempner says that using a DDP lab helps ensure that members get high-quality care at the lowest out-of-pocket cost. UHC contends that hospital outpatient labs cost on average 4 to 5 times more than independent labs, and in some cases as much as 1,000% more (see table on page 3).

### DDP Could Have Broad Reach

UHC's DDP program covers clinical lab tests and pathology services provided to non-hospital patients. Services excluded from the DDP program include lab testing performed in an emergency room or as part of an inpatient admission, and hospital outpatient testing that is billed as part of a bundled or global package.

In addition, the UHC DDP program applies only to its eight million fully insured commercial plan members. It does not affect UHC's self-insured commercial clients (18.6 million members), nor its Medicare Advantage (6.5 million members) or Medicaid (7.7 million members) plans.

Nonetheless, UHC has embarked on a big effort to educate ordering physicians about the benefits of using a DDP provider. It is also conducting outreach to members who have received services from a non-Designated Diagnostic Provider in the past 12 months. UHC has also posted online search tools for both doctors and members that highlight DDP labs. Using this search tool, Quest Diagnostics or LabCorp popped up at the top of the list of DDP labs in more than a dozen geographic markets checked by *Laboratory Economics*.

As a result, many UHC members may wind up having their test orders sent to a DDP lab regardless of their health plan.

UHC's DDP benefit design has so far been approved in 21 states, including Connecticut, Florida, Georgia, Indiana, Michigan, Ohio, Oregon, etc. Big states where it has not yet been approved include California, New York and Texas. "We continue to look for opportunities to expand access to this benefit so more members can take advantage of the cost savings," according to UHC's Lempner.

### Big Labs Dominate DDP

DDP labs must meet specific pricing requirements and be accredited (e.g., CAP or Joint Commission). UHC says there are currently more than 6,000 DDP locations, including PSCs, nationwide.

The list of DDP labs is dominated by the national labs and large hospital-owned independent labs. Labs that have received the DDP designation include ACL Labs, ARUP Labs, Bako Diagnostics,

BioReference Labs, Enzo Clinical Labs, Healthlab (part of Northwestern Medicine), HNL Labs, Joint Venture Hospital Labs, Labcorp, Mayo Clinic Labs, NeoGenomics, PathGroup, Poplar Healthcare, Quest Diagnostics, Sonic/CPL, TriCore Reference Labs, etc.

UHC says that in-network labs are still able to apply to become a DDP. However, one apparent requirement is for hospital outpatient labs to switch to lower-paying ancillary service/independent lab fee schedules. Below is some cost information that UHC provided for Atlanta, Cleveland and Nevada on three common lab tests. The chart compares the rates for DDP outpatient hospital labs versus non-DDP outpatient hospital labs. Lower rates translate to lower out-of-pocket costs paid by UHC members that must meet deductibles.

For example, a UHC member in Atlanta with a deductible to meet would pay \$7.98 for a strep test performed by a DDP hospital outpatient lab compared with paying \$23.94 for a non-DDP hospital outpatient lab.

On average, the rates paid to DDP hospital outpatient labs are about 50% to 60% of the Medicare Clinical Laboratory Fee Schedule (CLFS) for 2022. In comparison, the rates paid to non-DDP hospital outpatient labs are an average of more than double Medicare CLFS rates.

#### Cost Comparison of DDP Hospital Outpatient Labs vs. Non-DDP Hospital Outpatient Labs

<i>DDP Status (location)</i>	<i>Strep Test CPT 87880</i>	<i>Comprehensive Metabolic Panel CPT 80053</i>	<i>Glucose Test CPT 82947</i>
DDP Hospital Lab (Atlanta)	\$7.98	\$6.33	\$2.03
Non-DDP Hospital Lab (Atlanta)	\$23.94	\$19.00	\$6.09
DDP Hospital Lab (Cleveland)	\$7.98	\$6.33	\$2.03
Non-DDP Hospital Lab (Cleveland)	\$31.92	\$25.32	\$8.12
DDP Hospital Lab (Nevada)	\$7.98	\$6.33	\$2.03
Non-DDP Hospital Lab (Nevada)	\$47.88	\$39.00	\$12.18
Medicare CLFS Rate	\$16.53	\$10.56	\$3.93

Source: *Laboratory Economics* from UnitedHealthcare and CMS

#### CAP Urges UHC To Cease DDP

In a January 26 letter, the CAP, along with the American Medical Association, the American Academy of Dermatology and other physician trade groups, asked UHC to permanently cease implementation of the new DDP program.

UHC took some constructive steps in delaying and redesigning its DDP program, but the new design still has deficiencies, according to Jonathan Myles, MD, Chair of CAP's Council on Government and Professional Affairs. CAP is urging UHC to withdraw the DDP program altogether and rework it using input from medical and hospital organizations. CAP is concerned that the current plan will disrupt long-standing relationships between ordering physicians, pathologists and patients. Myles says that UHC has not yet responded to CAP's letter [as of February 10], although he does expect a response soon.

Myles says that the new tiered benefit design will have a disproportionate adverse effect on small independent labs and pathology groups that are unable to qualify for DDP designation. "An unintended consequence will be that longstanding professional referral relationships between treating physicians and local pathologists may be broken.... It puts referring doctors in the predicament of either choosing their preferred local lab or pathologist versus saving their patient money by redirecting testing to a distant lab," notes Myles.

## Spotlight Interview With siParadigm's Sherif Nasr, MD

**S**iParadigm (Pine Brook, NJ) is one of the largest independent hematopathology labs in the United States. The company was founded by its President and Medical Director, Sherif Nasr, MD, age 65, in 2004. Nasr is a hematopathologist who had previously been the Associate Medical Director of the Quest Diagnostics laboratory in Teterboro, New Jersey. *Laboratory Economics* recently spoke with Dr. Nasr about the history and future of siParadigm.



Sherif Nasr, MD

### Can you describe the early days at siParadigm?

In the early 2000s, I saw an opportunity to create a dedicated standalone hematopathology lab service. Back then, my employer, Quest Diagnostics, was more focused on high-volume automated clinical lab testing and less interested in human-resource-intensive services like hematopathology. So, I resigned and raised capital by selling my stock and house. Using \$1.15 million in personal funds, I was able to open a 5,500-square-foot CLIA-certified hematopathology lab in northern New Jersey in July 2004. Later, I raised another \$350,000 from friends and family, but siParadigm has never raised money from professional investors or bank loans.

### What do current operations look like?

siParadigm now operates a single 30,000 square-foot CAP-accredited laboratory in northern New Jersey. Our test menu includes histology, immunohistochemistry, flow cytometry, cytogenetics (karyotyping & FISH), and molecular (including NGS) testing. About half of our testing involves comprehensive analysis of cancer cases through our branded product siPortfolio. We have a total of 180 employees, including six hematopathologists. We've outgrown our current lab and are looking to move into a bigger one.

### Do you offer Covid-19 testing?

Yes. We began performing Covid-19 PCR testing in April 2020. During the Omicron surge our test volume peaked in late December/early January at 15,000 tests per day. Average positivity rates hit a peak of 40% but are currently averaging about 14%. We expect to continue offering Covid-19 PCR testing and are also looking to expand our microbiology test menu. We're also seeking to perform Covid-19 PCR testing for smaller independent labs at client pricing as low as \$22.50 per test.

### Are you using digital pathology & AI for clinical diagnostics?

We use Leica whole slide scanners and started getting serious about digital pathology about two years ago. Right now, we're performing it primarily for our TC-only clients for immunohistochemistry interpretations.

siParadigm employs an IT staff of 35 people in Pakistan that manages our LIS and is developing AI applications for FISH testing, karyotyping, flow cytometry gating and bone marrow morphology and peripheral smears. Our Chief Technology Officer is Hasan Sajid, PhD, who is also Chairman, Department of Robotics & AI at the National University of Science and Technology in Islamabad, Pakistan.

### Has siParadigm made any acquisitions?

We acquired the clinical laboratory business of Cancer Genetics Inc. (Rutherford, NJ) for about \$1.5 million in July 2019. This business, which focused on flow cytometry and genetic markers for cancer, was merged into our existing lab in northern New Jersey.

We also took over servicing Genoptix's clients in Puerto Rico when they chose to exit this market after Hurricane Maria in September 2017. It's a challenge because reimbursement rates in

Puerto Rico are much lower than for mainland U.S. [Genoptix was acquired by NeoGenomics in December 2018.]

**What are your goals for 2022?**

We currently employ 15 sales reps and we're hiring five additional reps per month. We hope to have 70 sales reps by the end of the year. We've always hired experienced sales reps from other labs and pharma companies. But now we are creating our own sales academy with a three-month program that includes training new reps at our lab combined with shadowing our experienced sales reps.

**What is your exit strategy?**

My goal is to have siParadigm reach \$100 million in annual revenue and then have an IPO. I think we can reach this level in about four years.

In preparation, siParadigm has been expanding its management staff. Last year, I hired Mohammed Khan as CEO to take over day-to-day operations. Khan's experience includes 17 years at Quest Diagnostics where he held a variety of positions including Chief Operating Officer at its Q<sup>2</sup> Solutions joint venture with Quintiles, and Regional Vice President for Quest's Great Lakes Region. siParadigm is also in the process of establishing a board of directors.

## BioReference Labs Goes Live With Digital Pathology Plus AI

**O**PKO's BioReference Labs (Elmwood Park, NJ) went live in December with new whole-slide imaging scanners from Leica Biosciences (Buffalo Grove, IL). The scanners have been integrated with a digital pathology solution, PathFlow, made by Gestalt Diagnostics (Spokane, WA). PathFlow is a cloud-based software system that has helped integrate BioReference's LIS, workflow and scanned slide images with artificial intelligence algorithms developed by MindPeak (Hamburg, Germany). BioReference is also using PathFlow for slide image management and archival storage.

BioReference is using MindPeak's AI tool (named BreastIHC) to detect and quantify breast cancer cells from digitized slide images with immunohistochemistry at its main laboratory in northern New Jersey. Pathologists can access their case and slide images securely on their computer monitors and use their mouse to outline regions of interest (ROI). All cells within this outlined ROI are instantly classified into positively stained tumor and unstained tumor cells. The panel of algorithms include five key tumor markers (ER, PR, Ki-67, HER2, and P53).

Eventually, Dan Roark, Chief Executive Officer, Gestalt Diagnostics, expects the AI algorithms to both automatically identify the regions of interest in addition to performing IHC scoring.

**Digital Pathology & AI Market Growth**

Separately, Roark says that after more than 10 years of limited adoption, digital pathology is finally starting to take off in the clinical market in the United States. Whole slide scanners have gotten quicker and less expensive. For example, it used to take 8-10 minutes to scan a slide but now takes as little as 30 seconds. But the biggest driver is the pathologist efficiency gains obtained when AI is applied to digitized slides. "The number of RFP requests we receive is exploding," says Roark.

**Worldwide Opportunities for U.S.-Based Pathologists**

The U.S. has more working pathologists per capita than most other countries. For example, there are approximately 20,000 actively practicing pathologists in the United States, according to the AMA. This works out to a ratio of one pathologist for every 17,000 people.

In comparison, with a population of 1.4 billion people, China has just 20,000 licensed pathologists, according to the Chinese Pathologist Association. Thus, China has only one pathologist per 70,000 people.

## Top 25 Flow Cytometry Labs

**O**PKO's BioReference Labs (Elmwood Park, NJ) is the top U.S. laboratory when it comes to flow cytometry test volume, according to data analyzed by *Laboratory Economics* from the Medicare Part B Carrier Files for 2019 (the latest year of data). BioReference performed total Medicare allowed service volume of 156,236 for five key flow cytometry codes (CPT 88184-TC, 88185-TC, 88187-PC, 88188-PC and 88189-PC) in 2019.

**Florida Cancer Specialists & Research Institute** (Fort Myers, FL) had total Medicare allowed volume of 139,849 service units for the five key flow cytometry codes in 2019.

**NeoGenomics** placed three lab locations (2 in California and 1 in Florida) on the top 25 list. On a consolidated basis, these three labs had total Medicare allowed volume of 204,934 service units for the five key flow cytometry codes in 2019.

### Top 25 Flow Cytometry Labs by Medicare Part B Carrier Allowed Volume for 2019

Laboratory	Location	Total Medicare TC Allowed Volume (88184 & 88185)	Total Medicare PC Allowed Volume (88187-88189)	Total Medicare TC & PC Allowed Volume
BioReference Labs	Elmwood Park, NJ	147,097	9,139	156,236
Florida Cancer Specialists & Research Inst.	Fort Myers, FL	133,865	5,984	139,849
NeoGenomics	Carlsbad, CA	97,106	6,755	103,861
NeoGenomics	Aliso Viejo, CA	53,814	10,840	64,654
Quest Diagnostics/Med Fusion	Lewisville, TX	63,252	0	63,252
Exagen Diagnostics	Vista, CA	30,915	15,989	46,904
New York Cancer & Blood Specialists	Riverhead, NY	46,036	0	46,036
Labcorp	Brentwood, TN	41,766	4,189	45,955
Quest Diagnostics Nichols Institute	San Juan Capistrano, CA	43,045	2,266	45,311
InformDx	Irving, TX	40,052	4,750	44,802
siParadigm	Pine Brook, NJ	39,235	2,501	41,736
Labcorp	RTP, NC	37,535	1,651	39,186
PathGroup/Pathologists Bio-Medical Labs	Lewisville, TX	32,364	5,654	38,018
NeoGenomics	Fort Myers, FL	33,472	2,947	36,419
Quest Diagnostics	Chantilly, VA	31,533	1,855	33,388
Labcorp	Shelton, CT	31,232	395	31,627
Cairo Diagnostics	White Plains, NY	29,248	1,229	30,477
PathGroup	Brentwood, TN	26,148	2,487	28,635
Quest Diagnostics	Teterboro, NJ	24,746	1,245	25,991
Sonora Quest Labs	Phoenix, AZ	23,096	2,237	25,333
Labcorp	Phoenix, AZ	22,890	1,942	24,832
Hematogenix Laboratory Services	Tinley Park, IL	22,795	1,253	24,048
Histopathology Services (dba Pathline)	Suffern, NY	18,745	1,671	20,416
Labcorp	Burlington, NC	18,512	894	19,406
Quest Diagnostics/AmeriPath	Shelton, CT	17,226	940	18,166
Total for Top 25 Labs		1,105,725	88,813	1,194,538
Total for All Labs and Pathologists		2,053,973	309,839	2,232,840

Source: *Laboratory Economics* from 2019 Medicare Fee-for-Service Provider Utilization & Payment Data

**Expert Market Research:** Laboratory Economics offers data-driven custom market research to define and size geographic markets (by MSA and nationally), estimate past trends and future growth opportunities for individual tests, and target potential customers by geographic location and medical specialty. Contact [jklipp@laboratoryeconomics.com](mailto:jklipp@laboratoryeconomics.com) for more info.

## PathGroup Acquires Pathology Consultants In South Carolina

**P**athGroup (Brentwood, TN) acquired Pathology Consultants Inc. (PCI-Greenville, SC) for an undisclosed sum in January. PCI operates a CAP-accredited pathology lab in Greenville, South Carolina. It has approximately 100 employees, including 31 pathologists.

PCI's biggest client is Prisma Health System of South Carolina (Greenville, SC). Prisma Health is the largest health system in South Carolina, formed by the merger of Palmetto Health and the Greenville Health System in November 2017. Prisma Health includes 18 hospitals and 270 physician practices. Its largest hospitals are Greenville Memorial Hospital (746 beds) and Richland Hospital (641 beds).

Pathology Consultants was founded by Arthur Dreskin, MD, and Don Kilgore, MD, in 1959. The group is currently led by David Schammel, MD, President and Medical Director, and Jesse Stafford, MD, who is Chief Clinical Officer for Laboratory Services at Prisma Health.

Ben Davis, MD, Chief Executive at PathGroup, says the PCI lab in Greenville will remain fully operational and that Drs. Schammel and Stafford will continue in their respective leadership roles at PCI.

The acquisition of PCI represents PathGroup's sixth deal since Pritzker Private Capital (Chicago, IL) took a majority stake in the company in the summer of 2016.

PathGroup now has more than 2,600 employees, including more than 225 pathologists, serving 100+ hospital contracts and thousands of physician clients. Annual revenue is now estimated to be more than \$500 million.

## Sema4 Pays \$473 Million To Buy GeneDx From OPKO Health

**S**ema4 (Stamford, CT) has agreed to acquire GeneDx (Gaithersburg, MD) from parent company OPKO Health (Miami, FL) for total upfront consideration of approximately \$473 million. The purchase price includes \$150 million of cash and 80 million shares of Sema4 valued at \$323 million. Sema4 may pay an additional \$150 million if GeneDx meets certain revenue-based milestones over the next two years (which will be payable in cash or Sema4 shares at Sema4's discretion). The deal is expected to close by June 30.

GeneDx was spun out of the U.S. National Institutes of Health in 2000 and was sold to BioReference Labs for \$17 million in 2006. BioReference Labs was then acquired by OPKO Health for \$1 billion in 2015.

GeneDx employs 100+ MDs/PhDs and 70 sales and marketing reps. It operates a CAP-accredited lab in Gaithersburg, Maryland, that specializes in whole exome and gene sequencing tests for rare disorders and diseases. GeneDx performed approximately 145,000 tests and generated \$116 million of revenue in 2021 (average revenue per test was \$800).

Sema4 is a publicly-traded company that operates two CAP-accredited labs in Branford and Stamford, Connecticut. Sema4 was spun out of Icahn School of Medicine at Mount Sinai and commenced operations in June 2017 as a for-profit genetic testing lab company. It specializes in non-invasive prenatal testing, newborn screening and oncology testing. In 2021, Sema4 generated an estimated \$204 million of revenue, including \$175 million from genetic testing and \$29 million for Covid-19 PCR testing.

Together, Sema4 and GeneDx will be one of the largest genetic testing lab companies in the U.S., with a projected \$350 million in proforma 2022 revenue and negative free cash flow of \$271 million. The combined company is not expected to turn profitable until 2025.

**Projected Pro Forma Financials at Sema4/GeneDx (\$ millions)**

	2025	2024	2023	2022	2021
Revenue <sup>1</sup>	\$817	\$636	\$475	\$350	\$291
Adjusted Gross Margin	50%	43%	33%	16%	5%
Free Cash Flow <sup>2</sup>	\$33	(\$99)	(\$199)	(\$271)	(\$226)

<sup>1</sup>Excludes Covid-19 testing revenue, which is being discontinued

<sup>2</sup>Proforma free cash flow excludes one-time transaction and integration expenses

Source: Sema4

Following close of the deal, Katherine Stueland, Chief Executive Officer of GeneDx, will become the Co-Chief Executive Officer focusing on commercial lab operations at Sema4. Eric Schadt, Founder and CEO of Sema4, will become Co-CEO of the combined company with his focus on pharmaceutical contracts and research and development.

**Sema4 to Exit Covid-19 Testing**

The acquisition of GeneDx comes as Sema4 winds down its national Covid-19 testing by the end of March. The company's contracts with the Connecticut Department of Public Health (CDPH) have recently come under scrutiny because of an investment by Annie Lamont, the wife of Governor Ned Lamont. Sema4 received a \$17.2 million contract from CDPH in July 2020 to provide Covid-19 testing at 15 locations and later received a no-bid contract worth \$8.4 million to provide testing at long-term care facilities. Ms. Lamont is managing partner at the private equity firm Oak HC/FT (Greenwich, CT), which is an investor in Sema4. CDPH says that the testing sites formerly managed by Sema4 have been transitioned to four other lab companies: Quest Diagnostics, Progressive Laboratories, Genesys Diagnostics and Wren Laboratories.

**Labcorp Signs Mega-Deal With Ascension (cont'd from page 1)**

The outreach lab assets being acquired by Labcorp had revenue of approximately \$150 million for Ascension last year. After the close of the transaction and the switch to Labcorp's lower-priced fee schedules, Ascension's outreach lab assets will provide Labcorp with an estimated \$100 million of annual revenue. Therefore, the purchase price of \$400 million equates to a multiple of roughly 2.7x last years revenue (\$400M/\$150M=2.7x) or 4.0x if based on estimated revenue for the first year under Labcorp's ownership (\$400M/\$100M=4.0x).

The lab management arrangement will cover Ascension's hospital labs in Alabama, Florida, Kansas, Maryland, Michigan, New York, Oklahoma, Tennessee, Texas, and Wisconsin. The lab management contract will bring Labcorp an estimated \$450 million to \$500 million of annual revenue.

Below we provide statistics on some of Ascension's biggest hospitals that Labcorp is expected to manage.

Hospital Name	Location	# Beds	Lab Dept Budget
Ascension Saint Thomas West	Nashville, TN	729	\$32,955,891
Ascension Saint John Hospital	Detroit, MI	604	\$31,820,036
Ascension Via Christi St. Francis	Wichita, KS	613	\$27,761,343
Our Lady of Lourdes Memorial Hospital	Binghamton, NY	175	\$27,601,229
Ascension Sacred Heart Pensacola Hospital	Pensacola, FL	536	\$25,143,085
Ascension Saint Vincent's Birmingham	Birmingham, AL	401	\$24,555,008
Ascension SE Wisconsin Hospital-St. Joseph Campus	Milwaukee, WI	323	\$22,633,966
Saint John Medical Center	Tulsa, OK	495	\$21,413,136
Ascension Saint Agnes Hospital	Baltimore, MD	271	\$17,428,489
Ascension Seton Medical Center Austin	Austin, TX	391	\$11,449,864

Source: *Laboratory Economics* from Hospital Cost Reports for 12 months ended June 30, 2021



## Tips On Complying With The No Surprises Act

The No Surprises Act, which bars patients from receiving surprise bills directly from out-of-network (OON) providers, is facing a number of legal challenges from provider groups unhappy with the law's payment dispute resolution process. Even so, the law took effect Jan. 1, 2022, and clinical labs and pathologists need to take the appropriate steps to comply with its requirements.



*Mick Raich*

According to Mick Raich, President, RCM Consulting and Lighthouse Lab Services and Vachette Pathology, the act primarily prevents patients from being billed in emergency scenarios or non-emergency situations where the patient did not have reasonable access to an in-network provider. In such cases, patients will be responsible only for their in-network cost sharing responsibility. Payers and providers would then negotiate the remainder of the bill. However, the dispute resolution process remains a point of contention, with provider groups saying the process gives insurers too much power to set rates and further restrict their networks. Raich estimates between 10% and 20% of all lab and pathology test claims are out-of-network and subject to the No Surprise Act.



*Joyce Gresko*

The No Surprises Act requirements generally apply to services provided to individuals enrolled in group health plans, those with individual health insurance and Federal Employees Health Benefits plans. They do not apply to Medicare, Medicaid, Indian Health Services, Veterans Affairs Health Care or TRICARE. These programs have their own protections against high medical bills.

It is important to note that the No Surprises Act does not preempt a state law that already establishes a method for determining the amount payable to an out-of-network provider, says Joyce Gresko, a partner with Alston & Bird (Washington, DC) and counsel to the American Clinical Laboratory Association. Clinical labs and pathologists should be aware of balance billing laws in the states in which they operate and what topics they cover, notes Gresko.

To comply with the No Surprises Act, Raich and Gresko advise that clinical labs and pathologists take the following steps:

- **Post a notice about the No Surprises Act** or applicable state balance bill law publicly in your facility and on your organization's website, along with information on how to report violations. Also, ensure that hospitals and providers you contract with also have such notices posted. You should also be able to provide to patients a one-page notice that includes the requirements of the law.
- **Be prepared to provide a "good faith estimate"** in advance of scheduled services or upon request—this applies to uninsured and self-pay individuals. The estimate must include expected charges for the items or services that are reasonably expected to be provided in conjunction with the primary item or service, including items or services that may be provided by other providers and facilities. The document is to be a standalone document and can be either electronic or paper. It must be received at least 72 hours before a procedure is performed (if requested by the patient).

For the first year, CMS will exercise enforcement discretion in a situation where a good faith estimate does not include expected charges from other providers or facilities that will be furnishing services in conjunction with the main provider, notes Gresko. "This is a law that will take shape through guidance, which will come out gradually," she says. "There are still a lot of questions that providers have."

The Centers for Medicare and Medicaid Services has a number of provider resources available at [www.cms.gov/nosurprises](http://www.cms.gov/nosurprises), including a model disclosure notice.

## Quest Reports Record Full-Year 2021 Financial Results

Quest Diagnostics reported a record high net income of \$2 billion for full-year 2021, up 39% from \$1.4 billion in 2020. Quest's overall revenue increased by 14% to a \$10.8 billion, with acquisitions contributing approximately 2% to revenue growth. Quest's average revenue per requisition fell by 1.6% to an estimated \$50 per req. A summary of key topics discussed by CEO Steve Rusckowski and CFO Mark Guinan on a February 3 conference call follows.

### Rusckowski to Step Down as CEO

Quest has appointed James E. Davis, Executive Vice President, General Diagnostics, to be its next CEO, effective November 1, 2022. Davis, 59, will succeed Rusckowski, 64, who will have served as CEO for more than a decade. Rusckowski, who is currently Chairman, CEO and President, will continue to serve as Executive Chairman through March 2023.

Quest also announced that Mark Guinan, 60, Executive Vice President and CFO, plans to retire in 2022, following eight and a half years in the role.

### Covid-19 Testing Peak in mid-January

Quest's volume of Covid-19 PCR testing during the Omicron wave peaked in mid-January. Quest performed an average of 120,000 Covid-19 PCR tests per day in January with average positivity of 30+% but declining at the end of the month.

### Direct-to-Consumer Testing

Revenues for QuestDirect services nearly doubled to more than \$70 million in 2021, driven by both routine and Covid-19 testing. "We expect the non-Covid consumer diagnostic market will experience double-digit growth over the next several years. And we're on track to build a \$250 million direct-to-consumer business by 2025," according to Rusckowski.

Quest recently began offering online ordering for 50 tests at walmart.com. Test orders are reviewed by telehealth physicians at PWNHealth (New York City), which was acquired by the direct-to-consumer test marketer Everywell (Austin, TX) in March 2021. A QuestDirect cholesterol panel ordered through walmart.com, for example, is priced at \$59 plus a \$6 physician fee for PWNHealth.

### Professional Laboratory Services

Quest's professional laboratory service (PLS) business, excluding Covid-19 testing, exceeded \$500 million in annual revenue last year. This business provides lab management services to hospital labs. Quest's largest PLS contract is with Hackensack Meridian Health (HMH) in

New Jersey. Quest is managing lab operations at 11 HMH hospitals and 700 lab employees have transitioned to Quest. Approximately 30% of HMH testing volume has been shifted to Quest's new 250,000-square-foot mega lab in Clifton, New Jersey.

### Quest Diagnostics Financial Summary (\$ millions)

	2021	2020	% Chg
Total revenue	\$10,788	\$9,437	14.3%
Base lab testing revenue	7,724	6,416	20.4%
Covid-19 testing revenue	2,770	2,723	1.7%
Other revenue*	294	298	-1.3%
Operating cash flow	2,233	2,005	11.4%
Capital expenditures	403	418	-3.6%
Free cash flow	1,830	1,587	15.3%
Net income	1,995	1,431	39.4%
Diluted EPS	\$15.55	\$10.47	48.5%
# Employees	50,000	49,000	2.0%
Avg. revenue per employee	\$215,760	\$192,592	12.0%
Est'd number of requisitions	217.4	186.6	16.5%
Est'd revenue per requisition	\$49.75	\$50.57	-1.6%

\*Other revenue includes clinical trials testing, info tech services and testing for life insurance companies

Source: Quest Diagnostics and LE's estimates for number of reqs and average revenue per req.

## Labcorp Reports Record Full-Year 2021 Financial Results

LabCorp (Burlington, NC) reported record net income of \$2.377 billion for the full-year 2021, up 53% from \$1.556 billion in 2020. LabCorp's overall revenue increased by 15% to \$16 billion in 2021. Revenue from LabCorp's lab testing business increased by 12% to \$10.4 billion in full-year 2021, including an estimated 12.5% from increased volume and -0.5% from a small decline in average revenue per requisition. On February 10, LabCorp held a conference call with analysts and investors. Here are some comments on a few key topics from CEO Adam Schechter.

### Covid-19 Testing

LabCorp generated revenue of \$2.76 billion from Covid-19 testing in 2021, down slightly from \$2.78 billion in 2020. It performed approximately 30.5 million Covid-19 PCR tests and four million antibody tests last year. For 2022, Schechter is anticipating that LabCorp's Covid-19 testing revenue will decline by between 60% and 75%, while its base non-Covid testing business will increase by between 3.5% and 6%.

### Lab Test Pricing

Medicare CLFS rates were frozen in 2021 and again this year. "In terms of other [non-Medicare] pricing, we don't see any acceleration of pricing decline. We're going to try to see if there's any way to increase pricing in certain areas. That's not easy," noted Schechter.

### Inflation Pressure

"Labor and supply, there's no doubt that we're getting hit with significant inflation. Labor and supply is not something we take lightly. We're watching it very closely, and we're seeing wage increases and supply [price] increases. That's why we put in place the \$350 million LaunchPad initiative to help offset that. The issue that occurs is that you get hit with the labor and supply and the wage issues right away, and it takes you time to get the cost out," said Schechter.

### Acquisitions

Labcorp spent \$497 million on acquisitions in 2021. Deals included the purchase of the lab outreach business of North Memorial Health (Robbinsdale, MN), OmniSeq (Buffalo, NY), and Myriad's Vectra autoimmune testing business (Salt Lake City, UT). Pending deals include the \$400 million purchase of certain assets of Ascension Health lab outreach business and an agreement to pay up to \$575 million for Personal Genome Diagnostics Inc. (see *LE*, January 2022).

### Strategic Review Complete

Early last year, Labcorp hired Goldman Sachs to help review its business structure with the aim of boosting its stock price. Potential options had included selling or spinning off its Covance drug development business. Labcorp says the review is complete and that it plans to keep the Covance business. Among the moves that Labcorp is taking are initiating a quarterly dividend and authorizing a \$2.5 billion share repurchase.

### LabCorp Financial Summary (\$ millions)

	2021	2020	% Chg
Total revenue	\$16,120.9	\$13,978.5	15.3%
LabCorp Diagnostics	10,363.6	9,253.4	12.0%
Covance Drug Development	5,845.5	4,877.7	19.8%
Operating cash flow	3,109.6	2,135.3	45.6%
Capital expenditures	460.4	381.7	20.6%
Free cash flow	2,649.2	1,753.6	51.1%
Pretax income	3,126.6	2,219.1	40.9%
Net income	2,377.3	1,556.1	52.8%
Diluted EPS	\$24.39	\$15.88	53.6%
Est'd number of requisitions	194.0	172.5	12.5%
Est'd revenue per requisition	\$54.00	\$54.25	-0.5%
# Lab employees	43,500	42,000	3.6%
Avg. revenue per lab employee	\$238,244	\$220,319	8.1%

Source: Labcorp and *LE*'s estimates for number of reqs and average revenue per req.

## Lab Stocks Down 19% Year To Date

**T**wenty-four lab stocks have dipped by an unweighted average of 19% year to date through February 11. In comparison, the S&P 500 Index has fallen by 7% so far this year. The top-performing lab stocks thus far in 2022 have been Enzo Biochem, up 5%; Exact Sciences, up 3%; and Castle Biosciences, up 1%. Labcorp is down 12% and Quest Diagnostics is off 23%.

Company (ticker)	Stock Price 2/11/22	Stock Price 12/31/21	2022 Price Change	Enterprise Value (\$ millions)	Enterprise Value/ Revenue	Enterprise Value/ EBITDA
Enzo Biochem (ENZ)	\$3.36	\$3.21	5%	\$149	1.3	140.6
Exact Sciences (EXAS)	80.33	77.83	3%	15,027	8.5	NA
Castle Biosciences (CSTL)	43.46	42.87	1%	736	8.5	NA
Psychemedics (PMD)	7.04	7.02	0%	43	1.8	16.8
ProPhase Labs (PRPH)	7.08	7.17	-1%	102	2.6	NA
CareDx (CDNA)	43.20	45.48	-5%	1,939	7.0	NA
Myriad Genetics (MYGN)	26.13	27.60	-5%	1,814	2.5	NA
Labcorp (LH)	276.26	314.21	-12%	31,218	1.9	7.7
DermTech Inc. (DMTK)	13.12	15.80	-17%	162	15.0	NA
Sema4 Holdings (SMFR)	3.59	4.46	-20%	438	2.0	NA
Sonic Healthcare (SHL.AX)*	37.18	46.63	-20%	20,225	2.3	9.4
Quest Diagnostics (DGX)	132.37	173.01	-23%	19,655	1.8	6.9
Natera (NTRA)	69.58	93.39	-25%	5,944	10.5	NA
Exagen (XGN)	8.60	11.63	-26%	60	1.2	NA
Veracyte (VCYT)	29.94	41.20	-27%	1,978	10.6	NA
Guardant Health (GH)	71.31	100.02	-29%	7,423	21.6	NA
Invitae (NVTA)	10.81	15.27	-29%	2,922	6.7	NA
Fulgent Genetics (FLGT)	70.28	100.59	-30%	1,663	1.6	2.2
Biocept (BIOC)	2.45	3.62	-32%	29	0.4	6.3
NeoGenomics (NEO)	22.57	34.12	-34%	2,849	5.9	NA
Biosesix (BDSX)	3.48	5.29	-34%	79	1.1	NA
Interpace Biosciences (IDXG)	4.90	7.47	-34%	76	1.9	NA
Aspira Women's Hlth (AWH)	1.15	1.77	-35%	92	14.4	NA
Opko Health (OPK)	3.10	4.81	-36%	2,208	1.2	12.4
Unweighted Averages			-19%	\$65,640	5.5	25.3

\*Sonic Healthcare's figures are in Australian dollars

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

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