

LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

PathAI Buys Poplar Healthcare Management

PathAI (Boston, MA) has acquired Poplar Healthcare Management, the management service organization for Poplar Healthcare (Memphis, TN). In connection with the transaction, PathAI also signed a long-term agreement to receive professional services from Poplar Healthcare PLLC, which employs 25 pathologists. The acquisition of Poplar gives PathAI one of the nation’s largest independent pathology labs through which it can introduce its artificial-intelligence software to help pathologists more accurately detect and quantify cancerous cells from digitized biopsy specimens. *Continued on page 4.*

Medicare Rates For Pathology Services To Get Nicked

Medicare professional component (PC) and technical component (TC) rates for most pathology services will be cut by a few percent next year, according to the newly released Proposed Medicare Physician Fee Schedule (MPFS) for 2022. For example, the national Medicare rate for 2022 (unadjusted for geographic location) for the PC of CPT 88305 is proposed to be cut by 5% to \$35.94, while the TC will remain the same at \$33.92. Overall, the proposed global rate for CPT 88305 will decline by 2% to \$69.86. *Continued on pages 2-3.*

Blue KC Sues GS Labs For Alleged Price Gouging

Blue Cross Blue Shield of Kansas City has filed a lawsuit accusing GS Labs LLC (Omaha, NE) of charging grossly inflated prices (e.g., \$380) for rapid antigen tests for Covid-19. In total, GS Labs has submitted more than \$9 million in claims to Blue KC. *Full details on page 5.*

New Jersey Urology Opens Expanded Laboratory

New Jersey Urology (Bloomfield, NJ) has opened an expanded and renovated 7,900-square-foot CAP-accredited pathology lab at its headquarters in northern New Jersey. The former lab space, which was approximately 2,800 square feet, had opened in 2013 and was focused on prostate and bladder cancer biopsies, immunohistochemistry, urine cytology and FISH testing. The new lab has expanded to include next-gen sequencing (Illumina’s MiniSeq platform) for genetic markers for prostate and bladder cancer. In addition, the new lab has added ThermoFisher’s QuantStudio for PCR-based testing for Covid-19 as well as urinary tract infections (UTIs). The new lab (branded NJU Diagnostics) will receive specimens from NJU’s 156 providers (including urologists, nurse practitioners and physician assistants) at 60 offices in New Jersey and eastern Pennsylvania. *Continued on page 2.*

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New Jersey Urology Opens Expanded Laboratory *(cont'd from page 1)*

Design of the new lab and instrument selection was overseen by Adnan Savera, MD, Medical Director of NJU Diagnostics. Savera, age 54, joined NJU in January 2017. Savera completed his



Adnan Savera,
MD

pathology residency at Henry Ford Hospital (Detroit, MI), where he served as a genitourinary (GU) pathologist for eight years at their Vattikuti Urology Institute. His past positions also include Chief Medical Officer at PLUS Diagnostics (now part of Inform Diagnostics).

Savera says he was initially skeptical of specialty groups that opened inhouse pathology labs, believing most were overly focused on financial gains. He was convinced to join NJU because he was given full charge of the lab's business operations as well as all technical decisions (e.g., evaluation of ancillary lab tests, implementation of testing protocols and standardization of lab testing utilization throughout the organization).

NJU Diagnostics currently has 34 lab employees, including two full-time GU pathologists (Dr. Savera and Randah Al-kana, MD). The lab performs testing on approximately 1,000 new patient specimens per day, including roughly 35-40 prostate biopsy cases, 10-15 bladder biopsy cases, 140 urine cytology tests, 80 FISH tests plus some 700-800 clinical lab tests (e.g., PSA, testosterone, CBCs, etc.). Biopsy slides are prepared overnight and read the following day for 24-48-hour turnaround, according to Savera. "I'd put the quality of our prostate cancer grading up against any academic medical center in the country," says Savera.

Medicare Rates For Pathology Services To Get Nicked *(cont'd from p. 1)*

The reductions to pathologists and pathology labs are the result of a 3.75% decrease in the proposed conversion factor for 2022 plus budget neutrality adjustments needed to offset proposed rate hikes being given to primary care physicians. Overall, the College of American Pathologists (CAP) estimates that the proposed rates will reduce Medicare reimbursement to pathologists by 5% in 2022, while technical component reimbursement to pathology labs will fall by 6%.

Prostate Biopsies

The global rate for G0416 (Surgical pathology for prostate biopsy) is proposed to decrease by 1% to \$351.97; professional interpretation down 4% to \$171.62; technical component up 3% to \$180.35.

Immunohistochemistry

The global rate for CPT 88342 (IHC, first stain procedure) is proposed to decrease by 10% to \$95.38; professional interpretation down 5% to \$33.58; technical component down 13% to \$61.80.

The global rate for CPT 88341 (IHC, additional slide) is proposed to decline by 14% to \$80.60; professional interpretation down 5% to \$27.20; technical component down 18% to \$53.40.

The Medicare Clinical Laboratory Fee Schedule

Following a one-year freeze in 2021, Medicare rates for most high-volume test codes on the Clinical Laboratory Fee Schedule (CLFS) will see a 10-15% reduction in 2022. In addition, the second PAMA survey reporting cycle begins next year. Labs are required to collect their private payer payment data from the period Jan. 1, 2019, through June 30, 2019, and report that data to CMS in the first quarter of 2022. CMS will use this data to calculate CLFS rates for 2023-2025.

Proposed Medicare Rate Changes for Key Pathology Codes for 2022

<i>CPT/HCPCS</i>	<i>Short Description</i>	<i>Proposed 2022¹</i>	<i>Actual 2021²</i>	<i>Proposed Rate % Change</i>
88112-Global	Cytopathology, cell enhance technique	\$66.83	\$67.69	-1%
88112-26	Cytopathology, cell enhance technique	26.87	27.91	-4%
88112-TC	Cytopathology, cell enhance technique	39.97	39.78	0%
88184-TC only	Flow cytometry/1st marker	68.18	69.79	-2%
88185-TC only	Flow cytometry/each add'l marker	19.48	23.03	-15%
88187-26 only	Flow cytometry, read 2-8	34.93	36.64	-5%
88188-26 only	Flow cytometry/read 9-15	60.79	62.81	-3%
88189-26 only	Flow cytometry, read 16 & greater	81.61	85.14	-4%
88305-Global	Tissue exam by pathologist	69.86	71.53	-2%
88305-26	Tissue exam by pathologist	35.94	37.68	-5%
88305-TC	Tissue exam by pathologist	33.92	33.85	0%
88307-Global	Level V, tissue exam by pathologist	280.10	290.31	-4%
88307-26	Level V, tissue exam by pathologist	78.92	83.39	-5%
88307-TC	Level V, tissue exam by pathologist	201.17	206.92	-3%
88309-Global	Level VI, tissue exam by pathologist	421.15	441.75	-5%
88309-26	Level VI, tissue exam by pathologist	140.05	146.90	-5%
88309-TC	Level VI, tissue exam by pathologist	281.10	294.85	-5%
88312-Global	Special stains, group 1	107.14	113.05	-5%
88312-26	Special stains, group 1	25.52	26.87	-5%
88312-TC	Special stains, group 1	81.61	86.19	-5%
88313-Global	Special stains; group 2	78.92	81.65	-3%
88313-26	Special stains; group 2	11.75	12.21	-4%
88313-TC	Special stains; group 2	67.17	69.44	-3%
88331-Global	Pathology consult during surgery	98.74	104.68	-6%
88331-26	Pathology consult during surgery	59.78	62.46	-4%
88331-TC	Pathology consult during surgery	38.96	42.22	-8%
88341-Global	Immunohistochemistry (Add'l stain)	80.60	93.86	-14%
88341-26	Immunohistochemistry (Add'l stain)	27.20	28.61	-5%
88341-TC	Immunohistochemistry (Add'l stain)	53.40	65.25	-18%
88342-Global	Immunohistochemistry (1st stain)	95.38	106.08	-10%
88342-26	Immunohistochemistry (1st stain)	33.58	35.24	-5%
88342-TC	Immunohistochemistry (1st stain)	61.80	70.83	-13%
88360-Global	Tumor immunohistochem/manual	111.84	124.92	-10%
88360-26	Tumor immunohistochem/manual	40.30	42.22	-5%
88360-TC	Tumor immunohistochem/manual	71.54	82.70	-13%
88361-Global	Tumor immunohistochem/computer	110.49	124.22	-11%
88361-26	Tumor immunohistochem/computer	41.98	43.97	-5%
88361-TC	Tumor immunohistochem/computer	68.51	80.25	-15%
88377-Global	Morphometric analy, ISH (quant/semiaq)	359.36	424.65	-15%
88377-26	Morphometric analy, ISH (quant/semiaq)	61.80	64.55	-4%
88377-TC	Morphometric analy, ISH (quant/semiaq)	297.56	360.10	-17%
G0416-Global	Prostate biopsy, any method	351.97	354.16	-1%
G0416-26	Prostate biopsy, any method	171.62	178.65	-4%
G0416-TC	Prostate biopsy, any method	180.35	175.51	3%
G0452-26	Molecular pathology interpretation	44.33	46.41	-4%

Note: Rates presented in table are national rates (unadjusted for geographic location)

¹Payments based on proposed 2022 conversion factor of 33.58; ²Payments based on the 2021 conversion factor of 34.89

Source: *Laboratory Economics* from CMS

PathAI Buys Poplar Healthcare Management (*cont'd from p. 1*)

Poplar Healthcare was originally founded under the name GI Pathology in 1995 by three Memphis pathologists specializing in gastrointestinal pathology. Two of the co-founders, Jackie Makapugay, MD, and Pat Dean, MD, plan to continue to practice at Poplar, while the third, Susan Williams, MD, retired in 2014.

Over time, Poplar has expanded into dermatopathology, women's health, uropathology and other services. Poplar acquired Bostwick Laboratories (specializing in uropathology) in May 2017 and Genetics of Memphis (specializing in cytogenetics) in March 2017. *Laboratory Economics* estimates that Poplar's annual revenue is in the range of \$50 million and \$100 million. The acquisition price has not been disclosed.

Poplar's CEO James Sweeney will stay on as President of PathAI's newly formed diagnostics division, which will comprise Poplar's CAP-accredited laboratory in Memphis and its 350 employees.

Poplar has been transitioning to digital pathology since early 2020 through an agreement with Gestalt Diagnostics (Spokane, WA). Poplar's shift to digital pathology is now expected to accelerate, which will enable the implementation of PathAI's proprietary algorithms and clinical decision support tools, according to PathAI CEO Andy Beck, MD, PhD. PathAI has developed AI algorithms for the detection and quantitative IHC scoring for nearly all solid tumors, including bladder, breast, colorectal, lung and prostate cancers.

In addition, Beck says that the Poplar acquisition will broadly enhance PathAI's research and development efforts, both to support drug development and to support the development and distribution of AI-powered tests for clinical diagnostics.

PathAI, which has approximately 200 employees, has raised a total of \$255 million from outside investors since being formed in 2016. Most recently, PathAI raised \$165 million from a Series C financing in May 2021. The latest financing was co-led by D1 Capital Partners and Kaiser Permanente. Another dozen investors joined in the round, including Bristol Myers Squibb, Labcorp and Merck's Global Health Innovation Fund.

"It's becoming widely understood and accepted that AI will become a routine part of pathology in the not-too-distant future,"
Andy Beck, MD, PhD.

Fulgent Genetics Acquires CSI Laboratories For \$50+ Million

Fulgent Genetics Inc. (Temple City, CA) has acquired Cytometry Specialists Inc. (Alpharetta, GA), which does business as CSI Laboratories, for \$50 million in cash plus up to \$10 million more in potential future milestone payments.

CSI Labs was founded by its Chairman Ron Ghafary in 1997. The company operates a main CAP-accredited lab in Alpharetta, Georgia, and a smaller lab in Jupiter, Florida. CSI Labs has 180 employees, including 10 pathologists. It performs more than 400 types of cancer tests, with its highest volumes in flow cytometry. *Laboratory Economics* estimates that CSI Labs annual revenue is in the range of \$30-\$60 million.

Synergy Capital Investments (Atlanta, GA) obtained an equity stake and a board seat at CSI Labs in 2019.

Fulgent Genetics is a publicly traded company that operates genetic testing labs in Temple City, California, and Houston, Texas. The company reported net income of \$280.5 million in the six months ended June 30, 2021, versus \$1.4 million in the same period a year earlier; revenue skyrocketed to \$513 million from \$25 million. Billable test volume jumped to 5.3 million tests from 194,000 tests. Fulgent's incredible growth was primarily fueled by Covid-19 PCR testing. Its largest clients include the County of Los Angeles and San Bernardino County.

Blue KC Sues GS Labs For Alleged Price Gouging *(cont'd from p. 1)*

GS Labs is a CLIA-certified independent lab based in Omaha that was opened by its CEO Gabe Sullivan in August 2020. GS Labs specializes in Covid-19 rapid antigen and antibody tests, which it performs at 27 locations in 13 states.

Blue KC, which covers more than one million members in the greater Kansas City area, filed the lawsuit (case 4:21-cv-00525) on July 20, 2021, in the U.S. District Court for the Western District of Missouri.

Blue KC alleges that GS Labs submitted at least 11,149 claims totaling over \$9.2 million for Covid-19 tests performed as an out-of-network provider between November 2020 and June 2021. The average charge per claim is approximately \$825 and most include a rapid Covid-19 antigen test for \$388, a rapid antibody test also for \$380, plus an additional \$50 charge for specimen collection.

Blue KC notes that GS Labs' out-of-network rates for Covid-19 rapid antigen and antibody testing are nearly 10 times that of Medicare rates (respectively \$41 and \$45) and 20 times higher than the wholesale cost of the rapid test kits (<\$20 per test).

GS Labs Cash Rates for Covid-19 Testing

CPT Code	Description	GS Labs Cash Rate	Medicare Rate
87811	Covid-19 Rapid Antigen Test	\$380.00	\$41.38
86328	Covid-19 Rapid Antibody Test	\$380.00	\$45.23
87635	Low-thruput Covid-19 PCR Test	\$385.00	\$51.31
0202U	Respiratory Pathogen Large Panel (22 targets including Covid-19)	\$979.00	\$416.78
G2023	Specimen collection for Covid-19	\$50.00	\$23.46

Source: CMS, GS Labs and Blue KC lawsuit

Furthermore, Blue KC alleges that many of the test services provided by GS Labs were performed solely to generate fees. "There is no legitimate medical reason to routinely perform both rapid antigen and rapid antibody tests together," according to Blue KC.

Blue KC says that negotiations "reached an impasse, after GS Labs refused Blue KC's offer to accept reasonable rates and demanded that Blue KC pay its sham prices less a small discount."

Blue KC is seeking a judgment declaring "Blue KC and our members are not required to pay GS Labs' unreasonable, inflated reimbursement demands."

GS Labs Files Countersuit Seeking \$9.7 Million

In response, GS Labs filed a countersuit against Blue KC on August 5. The lawsuit accuses Blue KC of legal bullying and "reckless disregard for the law" in a baseless attempt to stiff GS Labs on payments legally owed after it provided rapid Covid-19 tests for more than 12,000 Blue KC members.

Kirk Thompson, a partner at GS Labs, says that the owners invested \$37 million to build and staff GS Labs, including establishing 27 rapid testing locations and hiring nearly 3,000 workers.

GS Labs contends that the CARES Act requires insurers to pay for Covid-19 testing for their members. "Blue KC has utterly failed to comply with the CARES Act—it refused to pay GS Labs' publicly posted cash prices or negotiate in good faith and instead blindsided GS Labs with this frivolous suit," according to the countersuit.

GS Labs is seeking full payment of \$9.7 million for 34,621 unpaid tests performed for 12,000 Blue KC members, plus compensatory damages and legal fees.

UHC's Preferred Lab Network Adds NeoGenomics and Sonic's CPL

Effective July 1, 2021, UnitedHealthcare (UHC) has added two commercial labs, NeoGenomics and Sonic's Clinical Pathology Laboratories, to its Preferred Lab Network (PLN). UHC says that labs in its PLN are chosen based on patient service center access, quality of care, and cost.

UHC says that its members still have access to roughly 300 other in-network independent labs. However, UHC says that tests ordered from its PLN are at a lower average cost than other lab providers. For example, pathology service for a biopsy in the PLN would cost about \$90 versus \$150 for an in-network lab. As a result, use of a PLN lab results in lower member out-of-pocket costs for deductibles and co-pays, according to UHC.

Right now, the biggest benefit to labs in UHC's PLN is increased visibility. PLN providers are highlighted in UHC's directories to make it easy for physicians and members to identify them.

UHC's Preferred Lab Network (effective 7/1/21)

- BioReference Labs/GeneDx
- Invitae Corp.
- Labcorp and subsidiaries
- Mayo Clinic Labs
- Millennium Health
- NeoGenomics
- Quest Diagnostics/AmeriPath
- Sonic Healthcare's Clinical Pathology Labs

Source: UnitedHealthcare

In addition, UHC has been offering the PLN with zero-dollar out-of-pocket charges for lab tests for its fully-insured commercial members (total 7.8 million members) since late 2019. UHC has also marketed this same benefit design to its self-insured employer groups (total 18.4 million members) since early 2020. However, it appears that self-insured groups are transitioning to this benefit design change very slowly.

New Law For Medi-Cal Aimed At Eliminating Retroactive Recoupments

On July 27, California Gov. Gavin Newsom signed a comprehensive health care budget trailer bill (AB 133), which prevents future retroactive reimbursement reductions and recoupments from labs and pathology groups that occur due to "a lack of timeliness in Medi-Cal updating their rates." In the past, Medi-Cal fee schedule rate changes have been chronically delayed, which has often led the program to seek retroactive recoupments from labs and pathologists—a major administrative and billing headache.

In addition, the new law has made a minor adjustment to the methodology used for setting Medi-Cal fee schedule rates for clinical lab tests and pathology services. Beginning on July 1, 2022, Medi-Cal rates will be based on the lowest of the following: 1) the amount billed; 2) the charge to the general public; 3) 100% of the lowest maximum allowance established by the federal Medicare program for the same or similar services; or 4) a reimbursement rate based on an average of the lowest amount that other payers and other state Medicaid programs are paying for similar clinical laboratory or laboratory services.

The California Department of Health Care Services (DHCS) will not adjust rates currently established on the Medi-Cal fee schedule that do not exceed the limitations mentioned above, according to a DHCS spokesman. Some labs and pathologists had hoped the new law would raise their Medi-Cal rates to 100% of Medicare rates next year, but it does not.

The DHCS spokesman confirmed that the DHCS will continue to conduct its triennial rate survey and adjust rates based on the average of the lowest amounts third-party payers are paying. The next rate survey will be based on third-party payer data collected from calendar year 2021, reported in 2022 and effective in July 2023.

Spotlight Interview With University Health's Stephanie Whitehead

University Health (UH-San Antonio, TX) includes the flagship University Hospital (650+ beds), almost two dozen clinics, long-term care facilities and county facilities (jails, refugee clinics) located throughout the San Antonio region. Clinical lab and pathology services are provided by UH Pathology Services, which has 332 employees and contracts with 19 pathologists. *Laboratory Economics* recently spoke with Stephanie Whitehead, Executive Director of Pathology Services.



Stephanie
Whitehead

Do you specialize in any particular areas of testing?

Yes, our hospital does bone marrow transplants, so we do bone marrow testing. Our transfusion department irradiates their own blood products. We have a HLA department that supports our transplant service line, and we also have a cystic fibrosis program, so we do sweat chloride testing.

What platforms do you use for Covid-19 testing?

We have two Roche Cobas instruments that we mostly use for batched and pre-op patient testing. We also have two Hologic Panthers mainly used for STAT samples. We use the GeneXpert Cepheid for “rapid” Covid as well as panel testing for Covid, Flu and RSV. We also use the BioFire Torch's Respiratory Virus Panel, which tests for an array of viruses (including Covid-19). We're using several different platforms of testing in an effort to combat the threat of reagent or testing supply unavailability.

What are your Covid-19 testing volumes?

In 2020, we did 104,998 Covid tests. Year to date, we have averaged about 10,000 per month. We currently send all positive samples to the University Health Science Center – South Texas Reference Lab for variant testing. The majority of recent positive samples sent for variant testing have been positive for the Delta variant.

Have you seen an increase in RSV and croup in children?

This past winter there was virtually no “flu season,” but now that many local and state mandates related to pandemic precautions, such as masking and building capacities, have been relaxed (and people are socializing more), we have seen an increased percentage of samples that are positive for one or more respiratory viruses – including Covid-19.

What are your annual test volumes?

Last year's volumes decreased due to the lower outpatient volumes related to the pandemic. In a normal year, we perform over 4 million tests. Our ambulatory areas are still working to normalize operations and return to baseline volumes. It's hard to predict volumes for 2021 and beyond because of the increase in Covid-19 cases and the ongoing unpredictability of the pandemic.

Are volumes and revenues growing?

In 2021, we started to see a return to what we saw in previous years. Prior to the pandemic, they were increasing. We hope to see at least 2-3% growth going forward.

Do you send out testing? Who is your primary reference lab?

We send out about 2% of lab orders. We have a number of reference labs, but our primary ones are ARUP Labs and University Health Science Center – South Texas Reference Lab. We mostly send out genetic testing and other esoteric testing not done in-house, such as quantiferon testing.

Do you use digital pathology and/or artificial intelligence?

No, we don't.

Are you experiencing any employee shortages?

Just like everybody, we face challenges. Some people have decided to retire early because of the pandemic, and there are not as many new people coming into the profession. Shortages are most acute in areas where testing is less automated, such as blood bank and microbiology.

We work closely with local MLT and CLS programs. During the recruitment process, we highlight the incentives provided to all UH employees, such as more paid time off, raises based on performance and continuing education reimbursement. Once we hire someone, we focus on retention. We have a laboratory career ladder, and we do a lot of team engagement, rewards and recognition.

What's the biggest difficulty you have with commercial insurers?

We are fortunate to have an entire team dedicated to contract management. The biggest complaint I hear from them is that payers don't always maintain their fee schedules, so there can be a difference between what you expect to get paid and what you actually receive.

How have you addressed issues of pre-authorization for genetic testing?

We hired a genetic counselor for laboratory testing, so we don't really have any problems with pre-authorization anymore. Her job is to review laboratory test orders, as well as algorithms. Our denials are way down, and we are proactive in utilization management, which helps eliminate unnecessary testing and costs.

What is your biggest challenge?

Our biggest challenge is real estate. Our health system is building a fourth tower, and as other service lines grow, there are more specimens, more supplies, but no more space. In 2020, we were able to convert an existing conference room into a dedicated Covid-19 testing lab. We have received approval to do additional renovations, but physical space is limited.

Medical Technologist Shortages Widespread

Medical technologists (MTs) have been in chronic short supply for at least the past 20 years. In the past, labs have used sign-on bonuses ranging from \$2,000 to \$5,000 to attract MTs. Last month, *Laboratory Economics* highlighted Alverno Laboratories (Hammond, IN) use of \$10,000 sign-on bonuses to try to fill hundreds of open positions. We thought it was unusual, but it's not. Both hospital labs and commercial labs across the country are offering sign-on bonuses ranging as high as \$10,000 to \$20,000 to fill open MT positions. Night shift and blood banking MT positions appear to be the hardest to fill. *Laboratory Economics* plans to take a deeper look at the lab industry's worker shortage in next month's issue.

Sample of Recent Sign-on Bonuses Being Offered to Medical Technologists

<i>Laboratory</i>	<i>Location</i>	<i>Position</i>	<i>Sign-on Bonus</i>
Atlanticare Regional Medical Center	Atlantic City, NJ	Medical Technologist	\$15,000
Beaumont Hospital	Troy, MI	Medical Technologist	\$15,000
Children's Hospital of Philadelphia	Philadelphia, PA	MT-Blood Bank	\$12,500
Desert Regional Medical Center	Palm Springs, CA	MT-Night Shift	\$20,000
JFK Memorial Hospital	Indio, CA	Medical Technologist	\$20,000
Labcorp	Kingston, NY	MT-Entry Level	\$10,000
MidHudson Regional Hospital	Poughkeepsie, NY	MT-Night Shift	\$10,000
Quest Diagnostics	Melville, NY	Medical Technologist II	\$10,000
UM Capital Region Medical Center	Largo, MD	MT-Blood Bank	\$10,000
West Florida Hospital	Pensacola, FL	Medical Technologist	\$10,000

Source: *Laboratory Economics*

Labcorp Mid-Year 2021 Review

Labcorp (Burlington, NC) reported net income of \$1.237 billion for the six months ended June 30, 2021, compared with a net loss of \$86 million in the same period for 2020. Overall, Labcorp's reported half-year revenue increased by 43% to \$8.002 billion.

Looking specifically at LabCorp's lab testing business, revenue was up 51% to \$5.123 billion, including approximately 1% gained from acquisitions. On July 29, the company held a conference call with analysts and investors to discuss its mid-year results. Here's a summary of some key topics discussed:

Covid-19 PCR Testing

Labcorp performed an average of more than 100,000 Covid-19 PCR tests per day in 1Q21, which declined to 54,000 in 2Q21. The company anticipates it will perform an average of 25,000 to 35,000 per day in the second half of this year. Labcorp's average reimbursement per Covid-19 PCR test is between \$85 and \$90. About 4% of the total Covid-19 PCR tests performed by Labcorp come from its home collection kit Pixel, which is sold at 6,000 Walgreens stores (retail price: \$124.99) as well as online stores like DoorDash and Instacart, according to CEO Adam Schechter.

Core Test Volume Trends

Labcorp's core testing volumes (excluding Covid testing) returned to above pre-pandemic levels in June, according to Schechter.

Acquisitions

Labcorp announced a deal to acquire the clinical lab outreach business of Minnesota-based North Memorial Health Hospital (NMHH-385 beds), including an agreement to provide management services to its inpatient lab. NMHH has an annual lab department budget of \$42 million, according to its latest Hospital Cost Report for 2019.

Labor Shortages

"I think everybody is facing a tough labor market in most industries as we speak. And we're just going to have to continue to find ways through LaunchPad and other ways to reduce costs to cover that in the future," said Schechter.

Strategic Review

Earlier this year, Labcorp hired Goldman Sachs to help it conduct a strategic review of its business structure. Potential options include the spin-off of its contract research organization (CRO) division, which provides clinical trial management services to pharmaceutical and biotech companies. Labcorp entered the CRO business through the acquisition of Covance Inc. for \$6.2 billion (enterprise value of \$5.6 billion) in 2015. Labcorp expects to complete its strategic review by year's end.

Labcorp Mid-Year Financial Summary (\$ millions)

Six months ended:	6/30/2021	6/30/2020	% Chg
Total revenue	\$8,002.2	\$5,592.6	43.1%
LabCorp Diagnostics	5,123.3	3,394.7	50.9%
Covance Drug Development	2,933.4	2,237.5	31.1%
Operating cash flow	1,644.8	574.5	186.3%
Capital expenditures	192.6	205.1	-6.1%
Free cash flow	1,452.2	369.4	293.1%
Net income	1,237.0	-85.6	NA
Diluted EPS	\$12.58	-\$0.88	NA
Est'd number of requisitions	93.4	70.3	32.9%
Est'd revenue per requisition	\$57.55	\$48.77	18.0%

Source: Labcorp and Laboratory Economics' estimates

Quest Diagnostics Mid-Year 2021 Review

Quest Diagnostics (Madison, NJ) reported net income of \$1.1 billion for the six months ended June 30, 2021, up 287% from \$284 million in the same period for 2020. Overall, Quest's reported half-year revenue climbed 44% to \$5.270 billion. Quest's first-half requisition volume increased by 34.7% with organic volume up approximately 30% and acquisitions contributing 4.7%. Revenue per requisition increased by 8.1% to an estimated \$48.40 per req. driven in large part by Covid-19 PCR testing. Here's a summary of some key topics discussed during the company's July 22 conference call with analysts.

Covid-19 Testing

Quest's peak in Covid-19 PCR testing occurred in early December at an average of about 165,000 daily tests. Test volume declined to 99,000 per day in 1Q21 and then 57,000 in 2Q21. Quest expects its Covid-19 PCR test volume to drop to an average of 20,000+ PCR tests per day in the second half of 2021. The company's average reimbursement per Covid-19 PCR test is currently approximately \$90-\$95.

Core Test Volume Trends

Quest's core testing volumes (excluding Covid testing) had essentially returned to pre-pandemic levels in June, according to CEO Steve Ruskowski. He said that prescription drug monitoring and toxicology testing remain laggards. Geographically, Massachusetts, Connecticut and New York City have been the slowest to recover.

Health Plan Contracts

During the quarter, Quest renewed its longstanding national contract with Aetna. In addition, for the first time in over a decade, Quest became an in-network preferred lab for Highmark BCBS in Delaware, which serves more than 450,000 members. Labcorp remains a preferred lab for Highmark BCBS in Delaware as well.

Acquisitions

On June 1, 2021, Quest completed its acquisition of the clinical lab outreach business of Mercy Health (St. Louis, MO), which serves providers and patients in Arkansas, Kansas, Missouri and Oklahoma, in an all-cash transaction for \$225 million.

Labor Shortages

"In terms of labor pressure, we certainly saw some of that, and we responded to it [through wage increases]. And that is built into the whole year. It's not accelerating at this point in our outlook in the back half," noted Chief Financial Officer Mark Guinan.

Quest Diagnostics Mid-Year Financial Summary (\$ millions)

Six months ended:	6/30/2021	6/30/2020	% Chg
Total revenue	\$5,270	\$3,649	44.4%
Routine clinical lab testing	2,182	1,757	24.2%
Covid-19 testing	1,339	606	121.0%
Gene-based & esoteric testing	1,326	935	41.8%
Anatomic pathology testing	270	210	28.6%
Other revenue*	153	141	8.5%
Operating cash flow	1,191	602	97.8%
Capital expenditures	170	165	3.0%
Free cash flow	1,021	437	133.6%
Net income	1,100	284	287.3%
Diluted EPS	\$8.38	\$2.09	301.0%
Est'd number of requisitions	105.7	78.5	34.7%
Est'd revenue per requisition	\$48.40	\$44.80	8.1%

*Other revenue includes life insurance testing and health information technology services (e.g., electronic health records, practice management and revenue cycle management)

Source: Quest Diagnostics and *Laboratory Economics'* estimates

Alverno Labs To Implement Artificial Intelligence For Pathology

Alverno Laboratories (Hammond, IN), which transitioned to digital pathology in 2019 when it implemented Philips IntelliSite Pathology Solution, now says it will add artificial intelligence to aid its pathologists in cancer diagnosis. Alverno will use the Galen AI system developed by Ibex Medical Analytics (Tel Aviv, Israel).

Ibex's Galen platform recently received the Breakthrough Device Designation from FDA, which will help fast track the clinical review and clearance process, and is CE marked in Europe for breast and prostate cancer.

Alverno is an independent lab owned by Franciscan Alliance and AMITA Health. Alverno manages a core lab and 32 hospital labs in Indiana and Illinois. It consults on 150,000 histological cases per year, which translates to more than 1.1 million tissue slides.

Capital Digestive To Open Bigger Pathology Lab

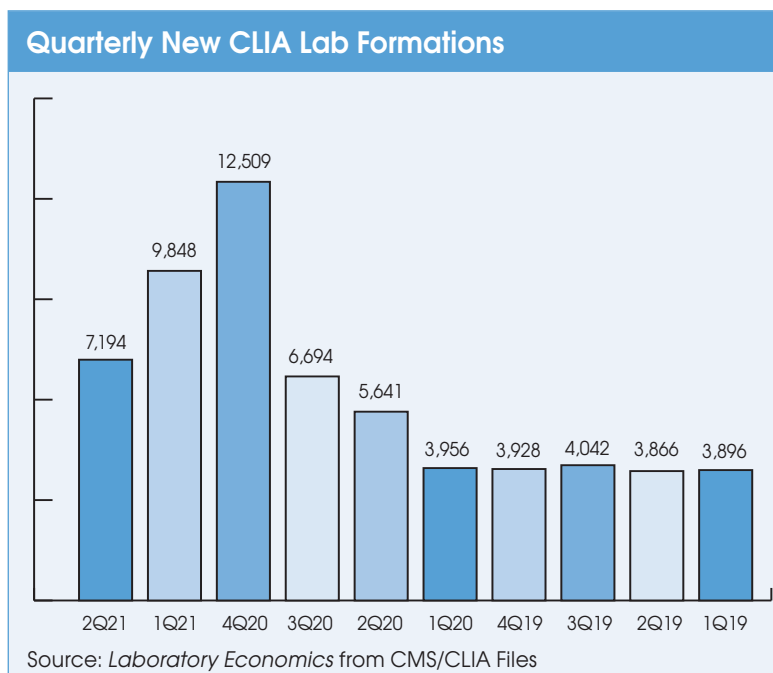
Capital Digestive Care (Silver Spring, MD) has announced plans to relocate and expand its pathology lab to Silver Spring, Maryland. The new lab will be 21,000 square feet and is expected to open in early 2022. In addition, the new lab will become a Roche Diagnostics Center of Excellence and will be expanding its clinical diagnostics testing menu.

Capital Digestive Care's current lab is CAP accredited and located in Bowie, Maryland. Its Medical Director Jeffrey Baybick, MD, had founded an independent pathology lab (Bay Labs) in 2004 that was merged into Capital Digestive Care in 2009.

Capital Digestive Care is the largest private practice gastroenterology group in the Mid-Atlantic. The group has 20+ offices in the greater Washington, DC area and includes more than 80 physicians, nurse practitioners and physician assistants, seeing 75,000+ patients and performing 35,000+ colonoscopies per year.

New Lab Formations Continue To Boom

The extraordinary demand for Covid-19 PCR, antigen and antibody testing continues to fuel a record number of new CLIA-certified lab formations, according to the latest CMS data analyzed by *Laboratory Economics*. More than 7,000 new CLIA lab certificates were issued in the second quarter (April 1-June 30, 2021). The all-time high (12,000+ new CLIA labs) occurred in the fourth quarter of 2020. The boom has created a huge demand for lab workers that had already been in short supply before the pandemic (see page 8).



Lab Stocks Up 8% Year To Date

Twenty-three lab stocks have risen by an unweighted average of 8% year to date through August 13. In comparison, the S&P 500 Index is up 18% thus far in 2021. The top-performing lab stocks so far have been Interpace Biosciences, up 187%; Fulgent Genetics, up 81%; and Myriad Genetics, up 66%. Labcorp is up 48%, Quest Diagnostics is up 24%, and Sonic Healthcare is up 29%.

Company (ticker)	Stock Price 8/13/21	Stock Price 12/31/20	2021 Price Change	Enterprise Value (\$ mill)	Enterprise Value/Revenue	Enterprise Value/EBITDA
Labcorp (LH)	\$302.04	\$203.55	48%	\$33,310	2.0	7.0
Sonic Healthcare (SHL.AX)*	41.45	32.15	29%	22,790	2.9	11.2
Quest Diagnostics (DGX)	148.22	119.17	24%	22,240	2.0	6.4
Exact Sciences (EXAS)	92.94	132.49	-30%	17,610	10.3	NA
Guardant Health (GH)	101.28	128.88	-21%	10,090	31.2	NA
Natera (NTRA)	100.91	99.52	1%	9,420	18.7	NA
Invitae (NVTA)	26.09	41.81	-38%	6,220	16.0	NA
NeoGenomics (NEO)	42.51	53.84	-21%	5,130	10.5	47.9
CareDx (CDNA)	69.85	72.45	-4%	3,470	13.7	NA
Opko Health (OPK)	3.68	3.95	-7%	2,740	1.4	14.4
Veracyte (VCYT)	40.55	48.94	-17%	2,700	17.2	NA
Myriad Genetics (MYGN)	32.79	19.77	66%	2,570	4.6	NA
Fulgent Genetics (FLGT)	94.21	52.10	81%	2,560	2.8	3.9
Castle Biosciences (CSTL)	64.44	67.15	-4%	1,520	19.4	NA
DermTech Inc. (DMTK)	34.21	32.44	5%	834	91.4	NA
Aspira Women's Hlth (AWH)	4.00	6.71	-40%	403	81.9	NA
Progenity (PROG)	1.66	5.31	-69%	234	2.9	NA
Biodesix (BDSX)	7.45	20.16	-37%	180	2.3	NA
Enzo Biochem (ENZ)	3.10	2.52	23%	139	1.2	18.5
Exagen (XGN)	12.28	13.20	-7%	113	2.4	NA
Interpace Biosciences (IDXG)	9.00	3.14	187%	91	2.7	NA
Biocept (BIOC)	4.00	4.44	-10%	54	1.2	NA
Psychemedics (PMD)	6.73	5.09	32%	43	1.9	NA
Unweighted Averages			8%	\$144,461	14.8	15.6

*Sonic Healthcare's figures are in Australian dollars

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

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