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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

Send-Out Test Expenses Jump 22%

Send-out testing expenses paid by hospitals and independent labs to the national reference labs (Quest, LabCorp, Mayo, ARUP and Sonic) increased by 22% in 2020, according to an exclusive survey conducted by *Laboratory Economics* in early July. Large labs (≥1 million total billable tests per year) saw their reference lab expenses rise by 20%, while the increase was 24% at smaller labs (<1 million total tests per year). Last year's increase exceeded the average historical trend of ~5% per year due to the pandemic and enormous demand for Covid-19 PCR tests.

Full details on pages 10-11.

UnitedHealth Seeks Dismissal Of Covid Test Lawsuit

UnitedHealth Group has filed a motion to dismiss Genesis Laboratory Management's lawsuit in its entirety with prejudice. The lawsuit alleges that UnitedHealth's failure to pay for 51,000 claims for Covid-19 testing that Genesis performed over the past year is in clear violation of the Families First Coronavirus Response Act (FFCRA) and CARES Act (see *LE*, June 2021).

In its response, UnitedHealth said, "Not only is there not private right of action under those statutes, but nothing in them requires UnitedHealth to resign itself to price-gouging of critical health care services during a national health emergency by opportunistic providers, let alone a provider that is suspected of improper billing practices."

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EKRA Law Applies To More Than Just Toxicology Labs

While The Eliminating Kickbacks in Recovery Act of 2018 (EKRA) was initially intended to target patient brokers who improperly profit from patients trying to recover from addiction, the law itself has been used more broadly as an enforcement mechanism against any labs that pay kickbacks for the referral of any kind of testing business. Particularly worrying is an EKRA provision that outlaws most traditional volume-based commissions paid to lab sales reps. "We are already seeing DOJ look at labs other than tox labs—and I do think that will continue. In short, the EKRA statute, as it now exists, applies to and is likely to be enforced against all labs," notes David Gee, a partner with Davis Wright Tremaine LLP (Seattle, WA).

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EKRA Law Applies To More Than Just Toxicology Labs (*cont'd from page 1*)

Although EKRA may still be used primarily in cases involving addiction treatment centers and the labs that service them, the U.S. Department of Justice (DOJ) has announced its prosecution of alleged EKRA violations in cases involving laboratory testing other than toxicology testing, says Gee. He is advising clinical labs to be cautious when structuring their compensation arrangements with their sales personnel. Such arrangements, if not structured properly, could potentially violate EKRA, as well as the Anti-Kickback Statute (AKS).


David Gee

The EKRA Law, passed as part of the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Communities Act (the SUPPORT Act), applies to all laboratories (as broadly defined by CLIA) whether or not they perform substance abuse testing. EKRA prohibits anyone from paying, receiving or soliciting any remuneration in return for referrals to recovery homes, clinical treatment facilities or laboratories.

While EKRA seems similar to AKS, there are key differences, says Gee. The AKS applies only to items or services covered by federal healthcare programs, while EKRA applies to services covered by any healthcare benefit program, public or private.

EKRA also has fewer safe harbor exceptions than the Anti-Kickback Statute. AKS has 11 statutory and 28 regulatory safe harbors, many of which overlap, while EKRA has only seven statutory safe harbors, some of which incorporate a specified AKS safe harbor: 1) Disclosed price discounts; 2) Certain payments to employees; 3) Part D drug discounts; 4) Personal services; 5) Co-pay waivers; 6) Qualified health clinics; and 7) Alternative payment models.

Significantly, EKRA does not incorporate the AKS safe harbor for any compensation paid under a *bona fide* employment arrangement but creates instead an exception for compensation to an employee or contractor that is neither determined nor varies by the number of individuals referred, the number of tests (procedures) performed or the amounts billed to or received from the healthcare benefit program, notes Gee.

EKRA also incorporates the AKS safe harbor for market value payments pursuant to personal services or management contracts, but that safe harbor likewise does not extend to compensation that is determined or varies by the volume or value of any referrals between the parties payable under the federal health care programs.

EKRA also carries substantially higher penalties than the AKS. AKS penalties include imprisonment of up to 10 years and a $100,000 fine per violation. EKRA penalties include imprisonment of up to 20 years and $200,000 per violation.

EKRA Cases

Since the law was enacted, there have been a number of cases brought by the federal government alleging health care fraud and abuse in which violation of EKRA is also alleged.

"There still is a heavy emphasis on opioid cases in the Department of Justice," says Alex Porter, a former DOJ prosecutor who recently joined Davis Wright Tremaine (Los Angeles, CA) as a partner. "EKRA is a powerful tool, and often it's used in conjunction with other tools. I've seen about a dozen EKRA prosecutions announced publicly, some related to opioids and sober living homes and some related to other kinds of services."


Alex Porter

Gee adds that some of the DOJ prosecutions are focused on pharmacogenomics, specifically related to DNA samples and genetic testing. "It's hard to say if these matters involve labs that also offer routine laboratory testing because the labs are not named

in the DOJ announcements I have seen. But the cases involving labs certainly involve more than just toxicology labs."

Among the EKRA cases that have been brought since it became law in 2018:

- In South Florida, 34 defendants were charged for their roles in schemes to defraud insurance programs out of more than $1 billion through money laundering, kickback (EKRA and the AKS) schemes and other fraud offenses.
- In New Jersey, 17 defendants were charged for their alleged roles in schemes to defraud insurance programs out of more than $1.2 billion. In one case, two owners of diagnostic testing laboratories and one marketer were charged for an alleged health care fraud and kickback (AKS and EKRA) scheme involving a total of $522 million in false and fraudulent claims. The owners of the lab were charged with paying kickbacks to a network of marketers to procure DNA samples for genetic testing that they knew to be medically unnecessary.

EKRA Convictions

The DOJ secured its first conviction under EKRA in January 2020. An office manager of a substance abuse treatment facility in Kentucky admitted to soliciting kickbacks from the CEO of a urine drug testing lab in exchange for the clinic's business. Among the bribes was a $4,000 check from the CEO of the lab. The 80-year-old manager of the treatment clinic cashed the check and when questioned about it later, lied about it and attempted to have the lab's financial records altered. In May 2020, the manager was sentenced to five months' imprisonment, followed by five months of home detention, and was ordered to pay a $55,000 fine.

"There have been other convictions, but I personally have not seen any other sentencing," notes Porter.

Despite the fact that EKRA was enacted nearly three years ago, no guidance has been issued on the statute by either the DOJ or OIG.

Potential Whistleblower Action?

Unlike federal AKS or Stark Law, EKRA includes no explicit provision that a violation of EKRA constitutes a false or fraudulent claim for purposes of the federal False Claims Act (FCA). As such, there is no statutory basis for whistleblowers to file complaints against their lab employers for violating EKRA, according to Gee.

Advice for Labs

Labs need to be aware not only of EKRA but also the AKS and other federal and state laws that may be implicated by payments to sales representatives. "Any time you are compensating salespeople on the basis of referrals, there is a potential problem," says Porter. "It's a minefield."

Gee adds that there are ways that laboratories can structure compensation arrangements so that they are not focused on testing volume or revenues. For example, compensation can be based on the number or types of clients introduced and serviced by the sales representatives, or on the number of visits to an account, or on the longevity of key client relationships. Labs can also elect to incentivize activities that will improve billing accuracy, efficiency and compliance, including effective client set up and in-service to better educate clients and reinforce the submission of complete patient demographic and insurance information as well as appropriate diagnosis documentation.

"I understand the frustration that labs have. Setting up new alternative compensation arrangements is not simple, and it's not familiar," says Gee. "But, given that it's been nearly three years since EKRA became law, it's time for all labs, not just tox labs, to take the steps necessary to move away from volume-based sales commissions."

Spotlight Interview with Pathline CEO Frank Moser

Pathline (Ramsey, NJ) is an anatomic pathology laboratory that primarily serves New Jersey and New York, but is in the process of expanding to serve other states. The lab has about 170 employees, including six pathologists. Another six pathologists work on a contract basis. Frank Moser joined Pathline in September 2019 and was named CEO in December of that year. Prior to Pathline, Frank spent 17 years in executive roles with Aegis Sciences Corp. (Nashville, TN). *Laboratory Economics* recently spoke with Moser about Pathline's growth plans.

Frank Moser

Can you give us more background on Pathline?
We've been serving hospitals and cancer centers since 2009. The company was sold six years ago to an investment firm, but is now owned by another firm, Monroe Capital out of Chicago. We have been primarily a regional player, but we are now focused on growing the business and expanding to other states. Covid delayed our original growth plan, but we are restarting it.

Do you specialize in particular areas of testing?
We have a couple of specialty areas—hematopathology, gastrointestinal and breast pathology.

How many clients do you serve?
Total clients are over 400, evenly split between Covid only and AP. We peaked at about 8,000 to 10,000 Covid PCR tests a day in January. We are still averaging about 800 to1,000 per day now.

What are your annual test volumes?
This year, Covid aside, we should do about 300,000 tests. In 2019, we did a little more than that. We are at about 95% of where we were pre-Covid. Cancer screenings are still down about 30% nationally, which we believe is part of that.

Are volumes and revenues growing?
By the end of the year, we'll be in the low double digits increase in volumes and revenues. In 2022 we are planning to continue to expand our geographic footprint. We never really did virology before, but we offer a combo test for Covid and flu and believe that volumes for that test will increase this fall.

Where are you planning to expand?
Mostly in the east coast, the mid-Atlantic, perhaps some in the mid-west. Our strategy is to find the right salesperson in a particular area and build our client base from there. We are also looking at launching women's health, and we have a pathologist, Douglas Charney, MD, with expertise in renal cancer, so we are exploring that as well.

What differentiates Pathline from the national labs like Quest/AmeriPath, Labcorp/Dianon, Sonic/Aurora Diagnostics?
Our goal is to be a boutique lab offering white-glove service and customize panels, requisitions and reports. We aim to out-service our competition. Our turnaround time for tech work with hospitals is 24 hours or less; for flow cytometry, it's 12 to 24 hours; molecular is three to five days. That is a metric that we measure quite closely.

Do you use digital pathology and/or artificial intelligence?
We recently brought the Leica digital pathology system on board. We are in the process internally of validating it, but we have not officially launched. We think it will be live by the end of the year. Many still have a hard time accepting it for primary diagnosis.

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What are the biggest difficulties you have with commercial insurers (like Aetna, BCBS, United, etc.)?
As an independent lab, it's a challenge to get the attention of insurers and tell your story. You must have large claims volume to get their attention. Access is the biggest problem we have. We're in network with almost all the major insurers in the Northeast. It has not been a challenge locally, but it may be nationally as we expand.

Tell me about your expansion plans.
We have a three-year detailed plan and a five-year "back of the envelope" plan. We want to do it methodically and properly so we can build our capacity. We are investing on the front end to prepare ourselves. Our strategic growth plan is to leverage our expanded sales team to sell our superior service, enhanced testing capabilities and industry-leading turnaround times. We have made significant investments to enhance/expand our medical and executive teams, upgrade our laboratory equipment/test menu and improve IT infrastructure to prepare for growth.

What do you see as your biggest challenges and opportunities?
Our biggest challenge is hiring technical talent. Lab techs are hard to find. Competition is tough. Many of those we hired for Covid testing we have been able to convert to other positions. In terms of opportunity, we believe that a high quality service-oriented lab can do a lot. We're looking at women's health, and we'll see what virology does beyond Covid. Our core business is cancer diagnosis and treatment testing—that's where we expect most of our future growth.

PathGroup Buys SkinDx

PathGroup (Brentwood, TN) has acquired Skin Diagnostics Group (SkinDx-Birmingham, AL) for an undisclosed amount. SkinDx, which has 61 employees, including five dermatopathologists, was founded by its Chief Executive, Alan Long, MD, in 2009. Former owners Dr. Long and Grant Eudy, MD, Medical Director, will continue in their current roles at SkinDx.

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

PathGroup now has more than 2,500 employees, including more than 180 pathologists, serving 100+ hospital contracts and thousands of physician clients. Annual revenue is now estimated to be more than $450 million.

PathGroup's Acquisition History

Date	Acquisition & Location	Description
Jun-21	SkinDx (Birmingham, AL)	5 dermatopathologists
Nov-20	Regional Pathology Associates (Victoria, TX)	2 pathologists and 10 hospital contracts
Sep-19	Southeastern Pathology Associates (Brunswick, GA)	45 pathologists and 22 hospital contracts
May-19	Pathologists Bio-Medical Labs (Dallas, TX)	45 pathologists and contract with BUMC
Jun-14	Southern Pathology Associates (Chattanooga, TN)	4 pathologists
Mar-12	Atlanta Dermatopathology (Atlanta, GA)	dermatopathology group
Dec-11	Pathology & Forensic Consultants (Fort Wayne, IN)	4 pathologists
Aug-11	Associates in Laboratory Medicine (Dalton, GA)	2 pathologists
Mar-99	Marin Medical Labs (San Rafael, CA)	5 pathologists
Mar-99	Bradley Pathology Services (Cleveland, TN)	2 pathologists
Sep-97	Associated Pathologists (Nashville, TN)	First deal adds 30 pathologists

Source: *Laboratory Economics*

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Alverno Labs Offering Up To $10K Hiring Bonus For MT/MLTs

Alverno Laboratories (Hammond, IN) is offering big sign-on bonuses as it tries to fill hundreds of open jobs. Alverno employs roughly 2,116 people and has about 288 openings, including 29 positions at multiple locations for midnight medical technologist (MT) and medical laboratory technician (MLT) positions. Alverno, which has had trouble filling positions because of a lack of qualified applicants, is offering the incentive through September 9. The $10,000 bonus will go to newly-hired MT/MLTs who stay on for at least 13 months. Alverno, an independent lab company that is owned by Franciscan Alliance and AMITA Presence Health, operates a central lab near Chicago and manages 30+ hospital labs in Illinois and Indiana.

XIFIN To Open East Coast Office, Expand Into Radiology Billing

The revenue cycle management firm XIFIN Inc. (San Diego, CA) is opening a new 32,500-square-foot office in Charleston, South Carolina. The new office is slated to open in early August. XIFIN plans to hire over 150 positions in South Carolina over the next two years, according to Brian Kemp, Vice President and Head of the Charleston Office. Most of the new jobs will be for billing and reimbursement specialists and customer service. Kemp says XIFIN is investing a total of $25 million, mostly related to new employee hirings, to open the Charleston office.

Meanwhile, Kemp says that routine testing levels at hospitals and independent labs are now running at 100% of prepandemic levels. The addition of Covid-19 PCR and antibody testing has pushed current overall volume levels to 125% of prepandemic levels.

Expansion Into Radiology Billing

Separately, XIFIN has acquired Computerized Management Services (CMS- Simi Valley, CA), which has 80 employees and provides practice management and billing services to hospital-based radiology groups and imaging centers. Through this deal, CMS has become a subsidiary of XIFIN. J. Daryl Favale, Chief Executive Officer at CMS, will continue to lead CMS as General manager, XIFIN Radiology Services.

XIFIN, which currently has 468 employees, was founded by its Executive Chair and CEO, Lâle White, in 1997. The private equity firm GTCR (Chicago, IL) acquired XIFIN in 2014. Avista Capital Partners (New York City) acquired XIFIN from GTCR in February 2020.

Eurofins To Buy DNA Diagnostics Center

Eurofins Scientific (Luxembourg) says that its subsidiary Eurofins Clinical Testing US Holdings Inc. has agreed to acquire DNA Diagnostics Center (DDC-Fairfield, OH) for an undisclosed amount. DDC operates a CAP-accredited lab near Cincinnati that specializes in direct-to-consumer genetic testing. DDC has 240 employees and expects to generate revenue of more than $55 million in 2021.

DDC's direct-to-consumer testing services include:

- **SpermCheck:** An FDA-cleared rapid point-of-care test for male fertility. Priced at $40.
- **HomePaternity:** A DNA paternity test. Cheek swab samples are taken at home and mailed to the DDC lab for testing. Priced at $99.
- **Peekaboo:** An early gender detection test for pregnant women. Pin-prick blood samples are taken at home and mailed to the DDC lab for testing. Priced at $69.

Following completion of the transaction, expected to close in the third quarter, DDC will continue to operate from its existing Cincinnati-area lab and headquarters. DDC is being sold by the private equity firm GHO Capital Partners (London, UK), which originally acquired it for $118 million in October 2015.

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Spotlight Interview With Paige CEO Leo Grady


Leo Grady, PhD

Paige (New York, NY) was founded by pathologists and scientists from Memorial Sloan Kettering Cancer Center in 2017. Paige develops artificial intelligence (AI)-based systems that help diagnose cancer. In early 2019, the company hired Leo Grady, PhD, as Chief Executive Officer and Board member. He had previously been Senior Vice President of Engineering at HeartFlow (Redwood City, CA), where he led development efforts for HeartFlow's 3D modeling software for coronary artery disease. He received a B.S. degree in Electrical Engineering at the University of Vermont and a PhD in Cognitive and Neural Systems from Boston University. Below is a summary of *Laboratory Economics'* interview with Dr. Grady in late June.

Who founded Paige?
The intellectual property related to the AI-based computational pathology used by Paige was initially developed by Thomas Fuchs, PhD, while he was Director of Computational Pathology at The Warren Alpert Center for Digital and Computational Pathology at Memorial Sloan Kettering (MSK). Fuchs co-founded Paige with David Klimstra, MD, Chairman of the Department of Pathology at MSK, in 2017.

Fuchs is Chief Scientific Officer at Paige. Klimstra will become our Chief Medical Officer effective August 1.

Paige currently has more than 100 employees, mostly in the United States, with a small, but growing, presence in the United Kingdom and Europe.

Where did Paige get the annotated pathology slides needed to develop its AI algorithms?
As part of spin-out from MSK, Paige signed a comprehensive license agreement, giving it exclusive access to the hospital's archive of 25 million annotated pathology slides and its intellectual property in computational pathology. To date, Paige has digitized more than five million slides from the MSK archive.

How much capital has Paige raised?
We've raised a total of $220 million to date, including $125 million raised in January from a series C financing led by Casdin Capital, Johnson & Johnson Innovation (JJDC) and KKR. Paige's largest shareholders also include MSK, Breyer Capital, Goldman Sachs and Healthcare Venture Partners.

Where do Paige's software programs stand with the FDA?
In early 2019, Paige received an FDA breakthrough designation for its software program for the automated detection of cancer in prostate biopsies. FDA clearance is expected to start with prostate cancer and then expand to additional cancers.

In addition, in December 2020, the company obtained two CE marks for software aimed at breast and prostate cancers, including the ability to rate tumor samples, deliver a prognosis and guide treatment planning.

Finally, Paige's digital pathology image viewer, FullFocus, received FDA clearance in July 2020. The clearance allows for use of FullFocus with the FDA-authorized Philips Ultra Fast Scanner and paves the way for use with additional scanners in the future.

How accurate are Paige's AI-based software programs?
A study recently published in the *Journal of Pathology* showed that Paige Prostate had 100% sensitivity and 100% negative predictive value (NPV) at the patient level when analyzing 661 prostate needle biopsy slides from 100 consecutive patients in a real-world setting.

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The study took place at Grupo Oncoclinicas (São Paulo, Brazil), which is the largest private provider of cancer care in Latin America and was the first institution in the world to fully deploy Paige digital and computational pathology products for routine use. (See Independent Real-World Application of a Clinical-Grade Automated Prostate Cancer Detection System, *Journal of Pathology*, June 2021.)

How about pathologist productivity gains?
For the Grupo Oncoclinicas study, Paige Prostate generated binary predictions, benign or suspicious for cancer. A benign prediction prompted no further action by a pathologist, whereas a classification of suspicious would prompt pathologist review and/or additional IHC to confirm the presence of a malignancy. Given its high sensitivity and NPV, and specificity of 0.78, Paige Prostate showed the potential to be used as a screening tool that flags suspicious slides needing pathologist review. Given that roughly 80% of prostate biopsy slides are negative, screening with AI could provide huge gains in pathologist productivity. Ultimately, the medical community will decide how best to use AI.

Won't digitizing slides and performing AI analysis disrupt workflow and slow turnaround?
The Grupo Oncoclinicas study showed that Paige Prostate could improve efficiency by an estimated 65.5%. The use of AI allowed the pathologists to focus their microscope time on those slides most likely to contain cancer. It can also save time by identifying specimen samples requiring recuts and/or additional staining prior to being viewed by a pathologist.

Will AI products like Paige Prostate speed the transition to digital pathology?
The adoption of digital pathology to date has moved very slowly. We estimate that only 5% of pathology slides in the U.S. are currently being digitized. Return on investment (ROI) has been the biggest obstacle. The transition to digital pathology requires significant investment in terms of capital expense, workflow changes, floor space, and image storage. Without added reimbursement, it's hard to make a business case for digitizing slides. However, AI-based tools that raise pathologist productivity provide an ROI for going digital.

Why is Europe ahead of the United States in terms of digital pathology adoption?
The regulatory process for digital pathology in Europe was quicker and there is a greater shortage of pathologists. Even so, the majority of pathology cases in Europe are still interpreted using traditional light microscopes.

Paige recently announced some contracts with big commercial pathology labs.
Yes. Under our new agreement with Quest Diagnostics, Paige's proprietary AI tools will analyze digitized slides from Quest and its AmeriPath and Dermpath businesses to develop new software products for diagnosing cancer and other diseases. The collaboration will initially focus on solid tumor cancers, such as prostate, breast, colorectal and lung. Assuming regulatory clearance, Quest plans to use approved software products in its pathology operations.

In the near term, the collaboration also intends to license the insights to biopharmaceutical and research organizations to aid biomarker discovery, drug research and development and companion diagnostics.

Separately, Inform Diagnostics (Irving, TX) has agreed to immediately start using Paige's FullFocus digital pathology viewer as well as our data management system for storing digital pathology slides.

How will the role of pathologists evolve over the next 5-10 years?
I expect there'll be less microscopy-based work in a more distributed model. But the role and visibility of pathologists may get elevated due to digital pathology and AI. Digital pathology images allow pathologists to communicate more visually with ordering physicians, while AI will increase their diagnostic accuracy thereby providing more value to physicians and patients.

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UnitedHealth Seeks Dismissal Of Covid Test Lawsuit (*cont'd from page 1*)

Genesis (Oakhurst, NJ) is a non-contracted, out-of-network provider for UnitedHealth. During the first few weeks of the pandemic, Genesis billed UnitedHealth its cash price of $256.65 for Covid-19 PCR tests, and then raised its price to $513 in mid-April 2020.

The outcome of this lawsuit could set a precedent that affects the ability of out-of-network labs performing Covid-19 testing to collect on hundreds of millions of dollars of outstanding claims from UnitedHealth and other insurers.

UnitedHealth initially paid Genesis its billed rates of $256.65 and then $513 for Covid-19 PCR tests. However, from June 2020 and onward, Genesis alleges that "United has been systematically denying payment."

Genesis filed its lawsuit against UnitedHealth on June 2 in New Jersey District Court (case no. 3:21-cv-12057). The amount in dispute is more than $20 million.

In its response, UnitedHealth says that Genesis unilaterally set its charge for Covid-19 PCR tests at more than five times the Medicare rate of $100. UnitedHealth also noted that Quest Diagnostics has a listed cash rate of $128.30, an amount only slightly higher than the Medicare rate for Covid-19 PCR tests.

UnitedHealth noted that "Genesis's brazenness even caught the eye of the *New York Times*, which ran an article exposing the lab's practices entitled "Two Friends in Texas Were Tested For Coronavirus. One Bill Was For $199. The Other? $6,408." [*NYT*, June 29, 2020]

Furthermore, UnitedHealth contends that regardless of Genesis's complaints about United's reimbursement process, Genesis is not the arbiter of compliance with the FFCRA and the CARES Act's provisions—Congress expressly delegated that responsibility to the Secretaries of Health and Human Services, the Labor Department, and the Department of the Treasury, so neither statute creates a private right of action."

UnitedHealth's motion to dismiss is scheduled to be brought before District Judge Zahid N. Quraishi on August 2. Unless otherwise directed by the Judge Quraishi, the motion will be decided on the papers and no appearances are required.

Genesis is being represented by King & Spalding LLP (Atlanta, GA), while Alson & Bird LLP (New York City) is representing UnitedHealth.

UnitedHealthcare Delays Lab Test Registry Protocol Indefinitely

After several postponements, UnitedHealthcare (UHC) announced on July 1 that it would delay implementing its planned clinical and pathology Laboratory Test Registry Protocol until further notice.

UHC's Laboratory Test Registry Protocol would have required in-network, freestanding and outpatient laboratory claims to contain a laboratory-specific, unique code for the overwhelming majority of lab tests and pathology services, in addition to the standard Current Procedural Terminology (CPT) codes. UHC had planned to deny payment for claims containing non-registered tests or panels starting January 1, 2022.

The American Hospital Association (AHA) and the College of American Pathologists (CAP) had opposed the insurer's lab test registry. AHA and CAP said that the new requirements would have overburdened hospitals, labs and pathologists with unnecessary administrative and reporting requirements.

Send-Out Test Expenses Jump 22% (*cont'd from page 1*)

The *Laboratory Economics Reference Testing Survey* was completed by a total of 84 labs, including 32 hospital labs, 28 independent labs, 13 physician-office-based labs, eight pathology groups/labs, and three "other" labs (pharmacy-based lab, freestanding emergency care and health department clinic). The overall average survey respondent had 201 employees and performed 6.3 million billable tests per year.

All surveyed labs sent an average of 14.9% of their total billable test volume to reference labs at an average total cost of $1.6 million in 2020. Overall, the most frequent send-out tests were toxicology testing, Next-Generation Sequencing (NGS) for cancer, and cytogenetics.

Large labs (≥1 million total billable tests per year) sent out an average of 10.6% of their volume and spent an average of $2.8 million on reference lab services. Their most common send-out tests include toxicology testing, testosterone, and kidney stone analysis.

Smaller labs (<1 million total tests per year) sent out an average of 18.6% of their volume and spent an average of $410,000. Their most common send-out tests include thyroid (TSH), Next-Generation Sequencing (NGS) for cancer, and Vitamin D.

Most Frequent Send-Out Tests by Lab Size

All Surveyed Labs	*High-Volume Labs**	*Low-Volume Labs***
1) Toxicology testing	1) Toxicology testing	1) Thyroid (TSH)
2) NGS panels for cancer	2) Testosterone	2) NGS panels for cancer
3) Cytogenetics	3) Kidney stone analysis	3) Vitamin D
4) Testosterone	4) Pap testing	4) HER2 (breast cancer)
5) Thyroid (TSH)	5) NGS panels for cancer	5) EGFR mutation testing
6) Vitamin D	6) Lyme Disease	6) Allergy panels
7) Pap testing	7) Tuberculosis (TB)	7) BRCA genetic testing
8) Kidney stone analysis	8) Methylmalonic acid (MMA)	8) Toxicology testing
9) HER2 (breast cancer)	9) Cytogenetics	9) PDL-1 testing
10) Methylmalonic acid (MMA)	10) Hepatitis testing	10) Oncotype DX

*Labs performing ≥1 million total billable tests per year.

**Labs performing less than1 million total billable tests per year.

Source: *Laboratory Economics Reference Testing Survey* (n=84, July 2021)

Sixty-five percent of all surveyed labs said they were actively trying to broaden their esoteric test menu and reduce send-outs to reference labs. Respiratory virus panels, Next-Generation Sequencing, procalcitonin and toxicology testing are the tests that most labs plan to bring in-house over the next year.

What are the biggest barriers to expanding your esoteric testing menu?

Low test volumes do not justify bringing in-house	60%
Inadequate reimbursement from Medicare and/or commercial insurance	43%
Budget constraints or lack of capital	33%
Esoteric testing reagents are too expensive to justify expansion	33%
Difficulty in hiring laboratory staff with necessary expertise	2%
Not enough floor space in laboratory	27%

Source: *Laboratory Economics Reference Testing Survey* (n=84, July 2021)

The primary reason why labs don't expand their testing menus to bring more referred tests in-house is low volume (cited by 60% of surveyed labs). Other factors include inadequate reimbursement (43%), budget constraints or lack of capital (33%) and esoteric test reagent costs (33%).

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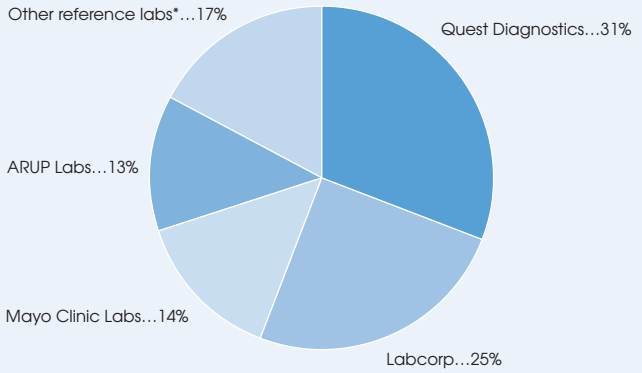
Reference Lab Market Share

The national market for reference testing services provided to hospitals and independent labs was an estimated $5.3 billion (excluding Covid testing) in 2020. This includes roughly $4 billion from hospitals and $1.3 billion from independent labs. Quest Diagnostics has an estimated 31% market share, followed by Labcorp, 25%; Mayo Clinic Labs, 14%; and ARUP Labs, 13%. Other reference labs, including BioReference Labs, NeoGenomics and Sonic Healthcare USA, share the rest of the market.

The $5.3 Billion U.S. Market for Reference Testing



*Includes BioReference Labs, NeoGenomics, Sonic Healthcare USA, etc.
Source: *Laboratory Economics* Reference Testing Survey and company financial reports

Thirty-five percent of all survey respondents said they use a group purchasing organization (GPO) to buy the majority of their reference testing. The GPOs used most frequently are Vizient (Irving, TX) and Premier Inc. (Charlotte, NC).

Vizient, formerly named VHA-UHC, has reference lab contracts with ARUP Labs, Labcorp, Mayo Clinic Labs and Quest Diagnostics.

Premier Inc. has contracts with ARUP Labs, Labcorp, NeoGenomics and Quest Diagnostics.

Only six survey respondents (7% of total) said they plan to switch their primary reference testing lab within the next 12 months.

Reference Lab Price & Service

Forty-five percent of surveyed labs said that Labcorp had the lowest prices, while 27% cited Quest Diagnostics.

ARUP Labs and Quest Diagnostics were each cited by 26% of surveyed labs as having the best service (i.e., answering questions and fixing problems).

In terms of overall value (i.e., price and service), 29% of surveyed labs selected Quest Diagnostics, while 27% chose ARUP Labs and 21% cited Labcorp.

Reference Lab Prices, Service and Value

	Lowest Prices	*Best Service*	*Overall Value*
ARUP Labs	10%	26%	27%
Labcorp	45%	21%	21%
Mayo Clinic Labs	3%	14%	12%
Quest Diagnostics	27%	26%	29%
Other reference labs*	15%	13%	11%

*Includes BioReference Labs, NeoGenomics, Sonic Healthcare USA, etc.
Source: *Laboratory Economics* Reference Testing Survey (n=84, July 2021)

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Lab Stocks Up 6% Year To Date

Twenty-two lab stocks have risen by an unweighted average of 6% year to date through July 16. In comparison, the S&P 500 Index is up 15% thus far in 2021. The top-performing lab stocks so far have been Interpace Biosciences, up 172%; Myriad Genetics, up 56%; and Labcorp, up 36%. Quest Diagnostics is up 13% year to date and Sonic Healthcare is up 22%.

Company (ticker)	Stock Price 7/16/21	Stock Price 12/31/20	2021 Price Change	Enterprise Value ($ mill)	Enterprise Value/ Revenue	Enterprise Value/ EBITDA
LabCorp (LH)	$276.45	$203.55	36%	$31,530	2.1	7.2
Sonic Healthcare (SHL.AX)*	39.09	32.15	22%	21,460	2.4	10.6
Exact Sciences (EXAS)	114.00	132.49	-14%	19,960	12.9	NA
Quest Diagnostics (DGX)	134.52	119.17	13%	19,850	1.9	6.8
Guardant Health (GH)	117.58	128.88	-9%	11,300	37.9	NA
Natera (NTRA)	113.12	99.52	14%	9,710	21.6	NA
Invitae (NVTA)	28.48	41.81	-32%	6,150	19.3	NA
NeoGenomics (NEO)	43.37	53.84	-19%	5,090	11.2	357.4
CareDx (CDNA)	78.83	72.45	9%	4,040	18.3	NA
Opko Health (OPK)	3.50	3.95	-11%	2,730	1.5	11.2
Myriad Genetics (MYGN)	30.79	19.77	56%	2,490	4.5	NA
Veracyte (VCYT)	38.13	48.94	-22%	2,340	19.0	NA
Castle Biosciences (CSTL)	64.99	67.15	-3%	1,470	21.6	NA
DermTech Inc. (DMTK)	33.41	32.44	3%	723	101.4	NA
Aspira Women's Hlth (AWH)	4.74	6.71	-29%	532	108.0	NA
Biodesix (BDSX)	11.41	20.16	-37%	298	4.3	NA
Progenity (PROG)	2.42	5.31	-54%	291	3.6	NA
Exagen (XGN)	13.27	13.20	1%	155	3.6	NA
Enzo Biochem (ENZ)	3.05	2.52	21%	139	1.2	18.6
Interpace Biosciences (IDXG)	8.55	3.14	172%	94	2.8	NA
Biocept (BIOC)	3.77	4.44	-15%	51	1.2	NA
Psychemedics (PMD)	6.81	5.09	34%	44	2.3	NA
Unweighted Averages			6%	$140,447	18.3	68.6

*Sonic Healthcare's figures are in Australian dollars

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

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