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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

Histolix Takes Aim At "Direct-to-Digital" Pathology

Histolix Inc. (Sacramento, CA), a spinout from UC Davis, has developed a desktop instrument for generating digitized images directly from thick (unsectioned) tissue biopsy specimens, either fresh or fixed, while skipping most of the traditional histology work steps. Histolix's "direct-to-digital" system can be performed in less than 10 minutes and has the potential to replace most current histology lab processes.
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UnitedHealthcare Moving Forward With DDP

Despite protests from CAP, AMA and other physician trade groups, UnitedHealthcare says that it will continue the rollout of its Designated Diagnostic Provider (DDP) benefit design for lab testing. "DDP became effective January 1 in 21 states and we continue to look for opportunities to expand access to this benefit so more members can benefit from the cost savings," according to UHC spokesperson Tracey Lempner. DDP labs must meet specific pricing requirements and be accredited. Lempner says labs are still able to apply and join the DDP program.
More details on page 10.

ACLA Awaits Appeals Court Decision On PAMA Lawsuit

Oral arguments were presented on February 25, and a ruling from the U.S. Court of Appeals for the District of Columbia Circuit could come any day.
Details on page 10.

Labcorp To Buy Prisma Health's Outreach Lab

Labcorp has agreed to acquire certain assets of Prisma Health's clinical laboratory outreach business for an undisclosed sum. In addition, Labcorp will provide technical support to Prisma's hospital labs. The deal is expected to close later this year. Prisma Health (Greenville, SC) is the largest health system in South Carolina.
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Labcorp To Buy Prisma Health's Outreach Lab (*cont'd from page 1*)

Labcorp says that it will offer expanded health plan coverage, additional access to rural markets and the potential for reduced out-of-pocket lab costs for Prisma patients. Additionally, Labcorp will collaborate with Prisma to provide same-day STAT testing in local communities.

However, anatomic pathology services and certain associated testing, as well as the pathologist relationship with all Prisma Health hospital labs are not affected by the Labcorp agreement.

Prisma operates 12 acute-care hospitals with a combined 2,947 beds and a total annual laboratory department budget of more than $130 million. Its largest hospitals are Greenville Memorial Hospital (Greenville, SC) and Richland Hospital (Columbia, SC).

In addition, Prisma employs 1,815 physicians and owns 300 physician practice locations in South Carolina. Its clinical lab outreach business collected more than $5 million of Medicare CLFS payments in the 12 months ended Sept. 30, 2020. *Laboratory Economics* estimates that Prisma's overall clinical lab outreach business has $25-50 million of annual collected revenue.

The deal with Prisma follows a similar but much larger agreement that Labcorp announced with Ascension last month (see *LE*, February 2022).

Snapshot of Prisma Health's Largest Hospitals

Hospital Name & Location	# Beds	Annual Lab Dept. Budget	Clinical Lab Medicare FFS Payments
Prisma Health Greenville Memorial Hospital (Greenville, SC)	864	$36,675,711	$2,275,032
Prisma Health Richland Hospital (Columbia, SC)	641	$59,665,977	$2,201,157
Prisma Health Baptist Hospital (Columbia, SC)	352	$13,092,385	$21,777
Prisma Health Tuomey Hospital (Sumter, SC)	283	$7,390,398	$135,912
Prisma Health Oconee Memorial Hospital (Seneca, SC)	304	$10,989,002	$552,202
Prisma Health Baptist Easley Hospital (Easley, SC)	109	$6,160,523	$416,256
Totals	2,553	$133,973,996	$5,602,336

Source: *Laboratory Economics* from Hospital Cost Reports for 12 months ended Sept. 30, 2020

Labcorp Completes Acquisition Of PGDx

Labcorp completed its previously announced (see *LE*, January 2022) acquisition of Personal Genome Diagnostics Inc. (PGDx-Baltimore, MD) on February 18. PGDx markets an FDA-cleared comprehensive tumor profiling test, PGDx ELIO tissue complete, that is covered by Medicare under the PLA code 0250U at a rate of $2,950. Labcorp paid $450 million in cash at closing and will pay up to an additional $125 million based on PGDx achieving future performance milestones. The $575 million purchase price, including contingent performance payments, is equal to 14.4 times PGDx's expected revenue of $40 million in 2022.

Quest Diagnostics Pays $85 Million For Labtech

The latest 10K annual report from Quest Diagnostics revealed that the company paid $85 million for its acquisition of Labtech Diagnostics (Anderson, SC). The deal, which closed on December 13, 2021, included cash consideration of $80 million and contingent consideration of $5 million dependent upon certain test volume goals. Labtech is an independent clinical lab specializing in allergy testing that serves physicians and patients primarily in South Carolina, North Carolina, Georgia and Florida. Labtech, which has 200 employees, was founded by its CEO/Owner Joseph Labash in 2011.

Histolix Takes Aim At "Direct-to-Digital" Pathology (*cont'd from page 1*)

For more insight into Histolix and its direct-to-digital technology, *Laboratory Economics* interviewed Alexander "Sandy" Borowsky, MD, Chief Medical Officer at Histolix and Director of Molecular Diagnostics at UC Davis.

Sandy Borowsky, MD

Who developed the technology behind Histolix?

It was developed by two of my colleagues at UC Davis, Richard Levenson, MD, and Farzad Fereidouni, PhD. Levenson is a pathologist and Vice Chair for Strategic Technologies at UC Davis Health. Fereidouni is an experimental physicist with expertise in the development of imaging instrumentation and computational methods for tissue and cellular microscopy applications.

In 2017, Levenson and Fereidouni received grants totaling $1.8 million from the NIH National Cancer Institute and Mark Foundation for Cancer Research to help develop a slide-free histopathology technique that can be used to create digitized images of minimally processed tissue samples.

The first prototype instrument was developed at UC Davis in 2018. And Levenson and Fereidouni co-founded Histolix to commercialize the technology in early 2019.

What is the workflow under the Histolix system?

A fresh tissue sample arrives at the lab and is cut with a razor blade or scalpel to prepare a flat surface for an image to be correctly captured in the desired plane. It then goes into a staining container that is dipped in staining solution for 30 seconds, followed by two quick washes in water.

The tissue specimen is placed into a "window" histology cassette and loaded into the Histolix microscope-based imaging system. The entire tissue section is scanned at high resolution. This digital image can then be immediately reviewed by a pathologist on their computer monitor, locally or remotely, via a standard digital pathology viewer. The whole process takes less than 10 minutes.

The Histolix system eliminates time-consuming steps associated with traditional histology such as tissue paraffin-processing—a step that generally takes 6-12 hours and is typically performed overnight—followed by embedding/mounting, microtome sectioning, mounting on glass slides, staining and cover-slipping, with an additional slide-scanning step to create a digital tissue image.

Can you describe the imaging technology used by Histolix?

We license a technology called FIBI (fluorescence imitating brightfield imaging) that was invented by Levenson and Fereidouni and patented by UC Davis. The FIBI technology captures surface-weighted microanatomy from thick tissue and produces diagnostic-quality images comparable to traditional H&E-stained slides.

Have any validation studies been published yet?

We recently completed an equivalency validation study that compared pathologist diagnoses from Histolix images versus whole slide images taken from conventional glass slides. One hundred cases, representing 22 different tissues (benign and malignant), were read by four pathologists, including pathologists from UC Davis, University of Vermont, Pathline LLC, and Sibley Memorial. The order of cases was randomized with a 30-day washout between reads.

The study results showed an overall major discordance rate of 2.1%. This beat CAP recommendations and previous FDA criteria established for clearance of digital whole-slide-imaging systems for primary pathology diagnosis set at <4%.

We will post the pre-print on medRxiv and submit for peer-review publication at CAP's *Archives of Pathology & Laboratory Medicine*.

Where will the Histolix technology be utilized first?
Several locations are obvious first priorities. These include radiology suites taking core needle biopsies and performing rapid onsite evaluations. A tech in the radiology suite could be trained to use our technology and then send images to a pathologist for near real-time interpretations.

In addition, our technology would be extremely useful during breast lumpectomy surgeries. Immediate pathologist margin assessments would reduce the need for repeat surgeries at rates of 10-20%.

It also has the potential to replace frozen sections, enabling faster interoperative diagnosis without loss or destruction of tissue.

Longer term, we believe Histolix also has the potential to replace most traditional histology and whole slide imaging.

When do you anticipate FDA clearance for clinical diagnostics?
We've begun planning a larger clinical study that would support an FDA application. Our goal is to receive clearance and begin commercialization in 2023.

What is the expected cost of the Histolix system?
We will offer a fee-per-scan service and envision the potential of adding AI reads and telepathology options into the fee-per-scan. If a capital purchase is preferred, the cost will be under $50,000.

Have you raised any capital from outside investors?
We raised $577,000 in early 2021 from a group of individual investors led by Ben Weiss, a former investment banker who has joined our board. We're currently seeking to raise $10-15 million from a Series A financing. These funds will be used to finance our next clinical study.

Who is the CEO of Histolix?
The company hired Rob Royea as CEO and President in January 2021. He has 30+ years of experience in healthcare technology, including executive roles at Cyrcadia Asia, Ziosoft Inc. and Siemens.

Who Will Win The Race For Direct-To-Digital Pathology?

In addition to Histolix, at least six other startup companies are developing "slide-free" technologies with the potential for direct-to-digital pathologist interpretations.

Alpenglow Biosciences (Seattle, WA), formerly named **Lightspeed Microscopy**, was spun-out of the University of Washington in 2018. Alpenglow's patented light-sheet microscope can rapidly image thick tissue specimens in 3D. It utilizes a microscope with two objective lenses set at 90 degrees to optically, rather than physically, section a specimen. The company was co-founded by its CEO, Nicholas Reder, MD, a pathologist, and Jonathan Liu, PhD, a mechanical engineering professor, both from UW. Alpenglow raised $4 million from a Series A financing led by Dynamk Capital (New York City) in 2021. The company has also received $1 million in NIH grant funding.

Instapath Inc. (Houston, TX) was spun-out of the biomedical engineering lab at Tulane University in 2017. The company relocated to Johnson & Johnson's JLABS at the Texas Medical Center Innovation Institute in 2019. The company's CEO and co-founder is Mei Wang, PhD. Instapath's technology utilizes structured illumination microscopy (SIM) and has been branded "Luci." Insta-

path received a $1 million grant from the National Science Foundation in early 2021 and raised another $1.8 million from private equity investors led by Draper Associates (San Mateo, CA) in 2019.

MUSE Microscopy Inc. was acquired by **Predictive Health Diagnostics Company** (PHDC-Irvine, CA) for a reported $29 million in November 2021. The MUSE microscope uses short-wavelength ultraviolet light which penetrates only microns-deep into tissue, eliminating the need for thin specimens placed on glass slides. In addition, the short-wavelength UV light excites many fluorescent dyes simultaneously enabling digital images comparable to traditional H&E glass slides. The MUSE technology was developed by Richard Levenson, MD, and Farzad Fereidouni, PhD, at UC Davis—the same pair that developed the FIBI technology used by Histolix. PHDC is a private company that markets two proprietary tests, PULS Cardiac Test and DIABETESpredict, and operates a CAP-accredited lab (dba Morningstar Laboratories) in Irvine, CA.

Applikate Technologies (Weston, CT) was founded by two scientists, Michael Levene, PhD, and Richard Torres, MD, from Yale University. Their patented CHiMP technology (clearing histology with multiphoton microscopy) is a method of staining and imaging whole samples without the need to slice them. Applikate has received a total of $3.4 million of grants from the NIH's Small Business Innovation Research (SBIR) program plus another $2.6 million from private investors.

Aquyre Biosciences (Cambridge, MA), formerly named LLtech, developed its CelTivity Biopsy Scanner System from research at ESPCI (the City of Paris Industrial Physics and Chemistry Higher Educational Institution). CelTivity employs full-field optical coherence tomography (FFOCT) for creating images from freshly excised tissue. In addition, its dynamic cell imaging (DCI) software highlights areas of increased intracellular activity which helps identify cancer cells. Aquyre has raised more than $20 million since being formed in 2007. Private equity investors include HealthTech Capital (Los Altos, CA).

Caliber Imaging & Diagnostics (Andover, MA) received FDA clearance for its Vivascope system in 2018. Vivascope is a reflectance confocal microscopy (RCM) point-of-care device that allows dermatologists to non-invasively visualize cellular structures within the skin/epidermis down to the supporting stroma in thin, optical slices. Caliber, formerly named Lucid Inc., had an IPO in 2011, but currently trades on the OTC Pink Sheets (LCDX: Market Cap <$3 million).

The Competition for "Slide-Free" Pathology

Company	Founded	Capital Raised[1]	Underlying Technology	Suitability for ROSE[2]	FDA Clearance
Histolix Inc. (Sacramento, CA)	2019	$2.4M	FIBI (fluorescence imitating brightfield imaging)	Yes	No
Alpenglow Biosciences/Light-Speed Microscopy (Seattle, WA)	2018	$5M	Tissue clearing and light sheet microscopy	No	No
Instapath Inc. (Houston, TX)	2017	$2.8M	Structured illumination microscopy	Yes	No
PHDC/MUSE Microscopy Inc.[3] (Irvine, CA)	2015	$29M3	Microscopy with UV surface excitation (MUSE) imaging	Yes	No
Applikate Technologies (Weston, CT)	2013	$6M	Clearing histology with multiphoton microscopy (CHiMP)	No	No
Aquyre Biosciences (Cambridge, MA)	2007	$20+M	Full-field optical coherence tomography (FFOCT)	Yes	No
Caliber Imaging & Diagnostics (Andover, MA)	1991	$7.8M	Reflectance confocal microscopy (RCM)	Yes	Yes (Vivascope)

1) Includes private equity and grants; 2) Rose: Rapid onsite evaluations; 3) MUSE was acquired by PHDC for a reported $29 million in November 2021.
Source: *Laboratory Economics* from companies and Crunchbase.com

BCBS of Minnesota Sues GS Labs for Covid-19 "Profiteering"

Blue Cross and Blue Shield of Minnesota (Eagan, MN) has filed a lawsuit against GS Labs (Omaha, NE) to recover more than $10 million in alleged overpayments for Covid-19 tests made since the start of the pandemic.

The complaint, which was filed in the U.S. District Court of Minnesota on March 1, alleges that GS Labs committed fraud against BCBSM by submitting tens of thousands of claims using inflated cash prices over the past year.

According to the Coronavirus Aid, Relief, and Economic Security (CARES) Act, in the absence of a contractual payment agreement, each Covid-19 testing provider is required to post specific cash prices on their public website, which insurers are then required to pay. BCBSM alleges that GS Labs consistently and intentionally posted inflated cash prices on their public website in order to charge significantly larger amounts to BCBSM than what it was willing to accept from individual cash-paying customers.

BCBSM contends that GS Labs consistently charged more than five times the median market rate for rapid Covid-19 antigen testing. GS Labs lowered its cash rate for Covid-19 antigen testing to $179 effective January 9, 2022, from its previous rate of $380. The Medicare rate for Covid-19 antigen testing (CPT 87811) is $41.

"After months of attempts at good-faith negotiations, we were unable to reach an agreement with GS Labs that would put in place appropriate Covid-19 testing practices at a fair price. It's egregious price-gouging like this that ultimately drives up the cost of health care for everyone," according to Scott Lynch, Senior Vice President of Pharmacy and Chief Legal Officer at BCBSM.

The lawsuit "represents more strong-arm gamesmanship by 'big insurance,' designed to hide their egregious failure to obey [federal law] by paying for tens of thousands of Covid-19 tests provided to their members," according to GS Labs spokesman David Leibowitz. "We look forward to litigating this absurd claim by BCBS of Minnesota in court."

GS Labs, which operates 27 rapid testing locations in 10 states, has tested more than 1.2 million people for Covid-19 since October 2020. The company has been sued by two other insurers over its pricing, including Premera Blue Cross (Mountlake Terrace, WA) and Blue Cross Blue Shield of Kansas City (see *LE*, August 2021). In addition, GS Labs filed a lawsuit in November 2021 against Medica (Minnetonka, MN) alleging the insurer has failed to pay full reimbursement for thousands of Covid-19 tests.

Redwood Toxicology To Pay $4.8M To Settle CT Medicaid Case

The U.S. Department of Health and Human Services and the Connecticut Attorney General's office have announced a civil settlement with Redwood Toxicology Laboratory (Santa Rosa, CA) to resolve allegations that it overcharged the Connecticut Medicaid program for lab tests.

Under the agreement, Redwood, which is owned by Abbott Labs, has agreed to pay $4.8 million covering claims submitted to the Connecticut Medicaid program between Jan. 1, 2015, and Feb. 24, 2018.

The government alleged that Redwood violated Connecticut's "Most Favored Nation" regulation, which requires that clinical labs do not bill the state's Medicaid program at rates higher than the lowest price the lab charges other payers for the same service. Specifically, the government alleged that Redwood regularly accepted payments from Connecticut Medicaid for certain urine drug tests at the rate of $38 per test, while at the same time charging other third parties from $2 to $10.50 for the same tests.

Spotlight Interview: Machaon Diagnostics' CEO and Founder Mike Ero


Mike Ero

Machaon Diagnostics, with labs in Berkeley, California, and New Orleans, is a clinical reference laboratory specializing in coagulation, platelets, complement, genetics and rare diseases. Named after a Greek healer who treated soldiers wounded in battle, Machaon has 55 employees, which includes 15 PhDs, one pathologist, one hematologist, 12 clinical lab scientists and support staff. *Laboratory Economics* recently spoke with Chief Executive and founder Mike Ero.

Tell me about Machaon Diagnostics.
We perform testing for hospitals, reference labs and clinics, and we also work as a contract research organization (CRO) to help pharmaceutical and biotechnology companies in their clinical trial drug development for rare diseases. About 90% of our clinical services are performed for patients who are in the ICU or critical care, who need a test result very quickly. There are over 1,000 hospitals that use our services across 50 states. We also receive samples from 17 different countries as well.

How many tests do you have on your test menu?
More than 500 tests, and about 150 to 200 of that is for our clinical lab work—the rest is utilized within our clinical trial service offerings. Our business is split about 50-50 between clinical lab testing and clinical trial services.

Why did you start Machaon Diagnostics back in 2003?
Prior to founding Machaon, I was Vice President at Coagulation Center Inc. (Oakland, CA), which was acquired by Quest Diagnostics.

I decided to start my own laboratory when I was 29, with a mission of "Saving more lives with lab tests." My original investment was $1 million to open a 2,500 square foot lab space. We started with a four-person lab—it was a real bootstrap operation.

I still own 100% of Machaon Diagnostics. Key employees are issued stock appreciation rights, which give them bonuses if the company performs well financially.

How many Covid-19 tests are you currently performing?
We do Covid-19 testing Monday to Friday, averaging 1,000 to 3,000 tests per week for the last 18 months. Out of the several hundred thousand Covid-19 tests we have done, all results have been released the same day the sample has been received. We use an assay called RT-LAMP.

What will you do with spare PCR testing capacity as Covid testing demand recedes?
Many patients were forced or chose to delay treatment for chronic diseases during the pandemic, but as those diseases may have worsened as a result, the need for our tests in the short-term has increased. Our non-Covid test volumes flattened out in 2020, but they have bounced back. By mid-2021, we saw a full return to normal growth.

We have deliberately kept a cap on how much of our business is defined by Covid as a business continuity strategy – it represents less than 20% of our overall revenue.

What sets you apart from other laboratories?
We generally only bring a test to market if we can be the fastest lab in the industry performing it. Most of our STAT tests are completed in a day, but there are some, like next generation-sequencing (NGS), that take 48 hours. This is still much faster (days and weeks) than what other labs can do. Our turnaround time saves lives—that's our mission.

Tell us about the expansion of your laboratory.
In December 2021, we expanded by opening a new 30,000-square-foot, state-of-the-art laboratory facility, tripling our previous footprint. We designed the new space with LEAN and Six Sigma laboratory design features to maximize the most efficient laboratory operation. We are also expanding into new areas, such as flow cytometry, minimal residual disease and tissue cultures.

Has Machaon made any acquisitions?
We acquired Louisiana Coagulation Laboratory in 2016 and moved it to a new lab space in New Orleans. They are a CAP-accredited lab and we hired their pathologist/owner, Gloria Coker, MD, as medical director.

Are your overall volumes and revenues growing year over year?
Since Machaon was founded in 2003, we have grown revenues each year. Last year, we did about twice the revenue that we did in 2020. This year we are on pace for our 30% annual growth target. Our goal is to hit annual revenue of $100 million within 10 years. We are in year three and on pace for that plan.

What is your biggest challenge?
Changes to the regulatory landscape of labs, especially if the FDA enforces oversight of lab-developed tests. If that gets fully embraced, it will have a stifling effect on innovation and would really tie the hands of labs across the U.S. Another challenge is if the services that we offer get picked up by other labs. That's one of the reasons we have a patent strategy—either for a test itself or for a key component. Some of our patents include the time to complete the test.

Spotlight Interview: Caris Life Sciences' David Spetzler, PhD


David Spetzler, PhD

Caris Life Sciences (Irving, TX) was founded by its Chairman and CEO, David Halbert, in 2008. The company sold its traditional anatomic pathology testing business, Caris Diagnostics (now named Inform Dx), to Miraca Holdings for $725 million in 2011. Over the past 10+ years, Caris has focused on molecular profiling of solid tumors while developing similar technology for blood-based cancer testing (aka liquid biopsies). The company currently has 1,500 employees, including 21 staff and five contracted pathologists, and annual revenue of more than $180 million. Last year, Caris raised $830 million from private investors to expand its laboratory footprint, further commercialize its tumor profiling tests and develop its new liquid-biopsy testing technology (see *LE*, May 2021). Here's a summary of *LE's* interview with David Spetzler, PhD, President and Chief Scientific Officer at Caris.

Can you describe Caris's laboratory operations?
Our main administrative offices and headquarters are in the Dallas area, and we currently operate three lab facilities in Phoenix.

We're in the process of building a new 115,000-square-foot laboratory in Dallas that will open early next year to accommodate growth.

We're also building a fourth lab in Phoenix that will be dedicated to blood-based cancer testing.

Can you describe what Caris does?
Caris currently focuses on molecular profiling of solid biopsies. Our Caris Molecular Intelligence platform analyzes all 22,000 DNA genes and 62,000 mRNA transcripts to help oncologists personalize cancer patient treatment and monitor for minimal residual disease--the small number of cancer cells in the body after cancer treatment that have the potential to come back and cause relapse.

How does your testing differ from competitors (Foundation Medicine, Tempus, etc.)?
Other molecular profiling labs are focused on hot spot testing with panels that contain at most a few hundred genes. As a result, they can miss a gene(s) that might be a driver of cancer.

For example, Caris tests for all three NTRK genes (1, 2, and 3). Although it is rare, the NTRK genes can fuse with other non-related genes which then produce new NTRK fusion proteins that promote uncontrolled cell growth and division in cancer cells. Testing for NTRK gene fusions in colorectal cancer tumors, for example, allows for the identification of patients who may benefit from TRK inhibitor therapy.

Isn't this expensive? Does Caris get pushback from insurers?
Caris currently has 80 insurance contracts covering 270 million lives. Most payers understand that the relative cost of testing is small when compared to drug treatments. Our testing typically averages about $3,000 per patient profile versus cancer treatments that can easily cost hundreds of thousands of dollars per year. With extensive coverage of these tests today, most patients out-of-pocket costs average less than $350. Aside from cost considerations, there is a huge clinical benefit to avoiding the toxicity of ineffective drugs that can make it harder for patients to recover.

Where are you in the development of a liquid biopsy?
We'll be starting validation testing soon and hope to launch an LDT for clinical testing by the middle of the year. Caris's liquid biopsy will be as comprehensive (all 22,000 DNA genes and 62,000 mRNA transcripts) as our tumor profiling. Initially it will focus on therapy selection and MRD monitoring.

What about a liquid biopsy for cancer screening?
We're working on a liquid biopsy panel for early detection that will screen for 30 different cancer types, including breast, colorectal, pancreatic and prostate.

One problem with today's screening tests is over-detection (false positives). Caris's liquid biopsy for early detection will test both plasma and the buffy coat—the white layer between plasma and red blood cells in centrifuged blood samples. This approach is more expensive, but it will greatly reduce the number of false positive test results that stem from the over-detection of mutations that look like they could be from cancer, but are actually from white blood cells (CHIP mutations), and thus do not indicate the patient has cancer. We expect to launch this once we have accumulated enough outcome data to be confident in our results.

Is Caris utilizing AI tools for pathology?
Yes. Caris employs some 50 data scientists and is developing AI algorithms internally using our archive of 350,000 cancer cases. We plan to utilize it in conjunction with our molecular profiling to further optimize cancer treatment decisions.

For example, standard first line therapy for colorectal cancer involves a choice between Folfox or Folfiri chemotherapy (in combination with bevacizumab). But, there is currently no good way to predict which of these therapies will work best for a particular patient beforehand. We have developed an AI-based predictor intended to gauge a colorectal cancer patient's likelihood of benefit from first-line Folfox+BV followed by Folfiri+BV versus the opposite order of treatment. Using two independent data sets (real-world evidence and Phase III study data), our AI algorithm improved the overall survival of patients by 17.5 months.

As another example, we are developing AI systems to identify the origin of a tumor sample based on molecular analysis. The origin of 5-10% of tumors is unknown, which leads to difficulty and delay in choosing a treatment regimen. We have applied advanced machine learning algorithms to our molecular profiling data for over 60,000 patients to identify signatures of genes to accurately predict tumor origin for greater than 90% of cases analyzed.

Will the combination of liquid biopsies and artificial intelligence make pathologists obsolete?
The availability of liquid biopsies and their full impact will occur gradually over the next several years. The development of AI algorithms requires enormous training data sets that don't exist right now. The pathologist will play a crucial role in patient care but their role will likely evolve.

UnitedHealthcare Moving Forward With DDP (*cont'd from page 1*)

In summary, UHC's DDP program highlights a subset of in-network labs with lower rates. The DDP program is for UHC's fully insured commercial members. However, UHC's heavy promotion of the DDP program is likely to have a spillover effect on lab choices made by referring physicians for other health plan members as well, notes *Laboratory Economics*.

Expansion of DDP Benefit Design to Imaging

In addition, UHC has created a separate DDP program that covers major imaging services, including MRI, CT, PET scan, MRA, and nuclear medicine. This new benefit plan was initiated for UHC's fully insured small group commercial plan members on January 1, 2022, with expansion to large group commercial members effective July 1, 2022. According to UHC, members that use a non-DDP imaging provider may incur higher deductibles and coinsurance.

ACLA Awaits Appeals Court Decision On PAMA Lawsuit (*cont'd from page 1*)

The American Clinical Laboratory Association's long-running PAMA lawsuit against the Department of Health and Human Services (DHHS) could soon get a decision from the U.S. Court of Appeals for the District of Columbia Circuit. Oral arguments were heard by a three-judge panel (DC Circuit Court Judges Patricia Millett, Robert Wilkins and Ketanji Brown Jackson) on February 25.

Lawyers from ACLA and DHHS were each given 10 minutes to present their case. Ashley Parrish, Partner at King & Spalding (Washington, DC), represented ACLA.

Parrish argued that the initial PAMA survey of lab rates improperly excluded data from nearly all hospital outreach labs and relied too heavily on data from the nation's largest commercial labs. The result was three straight years (2018-2020) of 10% rate cuts for most lab tests paid through the Medicare CLFS. ACLA wants the original PAMA data collection rules to be vacated (aka cancelled), which as a consequence would require a recalculation of the CLFS rates in place since 2018.

Oral arguments for DHHS were presented by McKaye Neumeister, an attorney for the U.S. Department of Justice. Neumeister argued that ACLA's case is moot given a 2018 rule from CMS that requires nearly all hospital outreach labs to report their private-payer payment rates in the next PAMA survey. [For the next PAMA survey, applicable labs are required to report their private-payer payment rates from 2019 to CMS in the first quarter of 2023. This data will be used to set Medicare CLFS rates for 2024-2026.]

Parrish rebutted DHHS by noting that the 2018 rule does not undo the damage from the initial PAMA survey.

There is no set timeline for the DC Circuit Court to announce a decision. And it's unclear what the impact of President Biden's nomination of Judge Ketanji Brown Jackson to the U.S. Supreme Court might have on the appeal, according to Tom Sparkman, Senior Vice President, Government Affairs and Policy at ACLA. Sparkman's comments came at ACLA's annual meeting in Washington, DC on March 9.

If the appeal is successful, the case will most likely be sent to the U.S. District Court for the District of Columbia to hear arguments and make a decision.

ACLA originally filed its PAMA lawsuit against DHHS in December 2017.

Meanwhile, Sparkman said that ACLA continues to lobby Congress for a long-term legislative fix to the methodology used to set Medicare CLFS rates under the 2014 Protecting Access to Medicare Act (PAMA). ACLA is seeking CLFS rates to be determined by a statistical sampling method that accurately accounts for private-payer lab test prices from independent labs, hospital outreach labs and POLs.

Comparing Productivity At Quest, LabCorp And BioReference

On a weighted basis, three publicly-traded lab companies collected average revenue of $51.58 per requisition in 2021. Average collected revenue per test was an estimated $17.19. Results for 2021 were greatly skewed by huge Covid-19 test volumes. The three lab companies performed a total of 72.4 million Covid-19 PCR tests and 7.7 million antibody tests in 2021.

The three companies—Quest Diagnostics, LabCorp and OPKO's BioReference Labs—generated a weighted average of $238,986 in revenue per employee in 2021. The average number of requisitions and tests processed per employee per year were 4,633 and 13,899, respectively. These figures are based on the total number of employees at the three companies, including all administrative, couriers, sales and marketing, and lab technical staff.

Productivity Stats at Quest Diagnostics, LabCorp and BioReference for 2021

2021 Financials	*Quest Diagnostics*	*LabCorp Diagnostics**	*BioReference Laboratories*	*Total*
Annual Revenue 2021	$10,494,000,000	$10,363,600,000	$1,607,106,000	$22,464,706,000
Operating Income 2021	$2,381,000,000	$2,988,500,000	$98,067,000	$5,467,567,000
# Employees**	45,000	44,000	5,000	94,000
Employee Efficiency				
Avg. Annual Revenue per Employee	$233,200	$235,536	$321,421	$238,986
Avg. Annual Operating Income per FTE	$52,911	$67,920	$19,613	$58,166
Requisition Stats				
Est'd Annual Requisitions 2021	217,500,000	194,000,000	24,000,000	435,500,000
Est'd Avg. Revenue per Requisition	$48.25	$53.42	$66.96	$51.58
Est'd Avg. Operating Income per Requisition	$10.95	$15.40	$4.09	$12.55
Est'd Avg. Reqs Processed per FTE	4,833	4,409	4,800	4,633
Test Stats				
Est'd Annual Test Volume 2021**	652,500,000	582,000,000	72,000,000	1,306,500,000
Est'd Avg. Revenue per Test	$16.08	$17.81	$22.32	$17.19
Est'd Avg. Operating Income per Test	$3.65	$5.13	$1.36	$4.18
Est'd Avg. Tests Processed per FTE	14,500	13,227	14,400	13,899
Billing Stats				
Accounts Receivable	$1,438,000,000	$1,193,800,000	$233,673,000	$2,865,473,000
Est'd Bad-Debt % (pre-ASC 606)	4% - 5%	4% - 5%	5% - 10%	5.0%
Days in Accounts Receivable	48	42	50 - 60	45 - 50
Revenue by Payer				
Private Patients	12.0%	9.5%	1.3%	10.1%
Medicare CLFS	7.0%	8.5%	10.3%	7.9%
Medicare PFS	1.0%	0.4%	1.5%	0.8%
Medicaid	2.0%	2.1%	2.0%	2.0%
Client Payers (physicians, hospitals, etc.)	33.0%	26.5%	52.5%	31.4%
Healthcare Insurers	42.0%	53.0%	32.4%	46.4%
Other	3.0%	0.0%	0.0%	1.4%
Covid-19 Testing				
PCR Test Volume for 2021	30,000,000	30,500,000	11,900,000	72,400,000
Antibody Test Volume for 2021	3,000,000	4,000,000	700,000	7,700,000

*Data is for LabCorp's lab testing business only. **Part-time employees counted as ½ FTE. ***Test volume stats assume an average of 3 tests per requisition.

Source: Company reports and *Laboratory Economics'* estimates

Lab Stocks Down 31% Year To Date

Twenty-four lab stocks have dropped by an unweighted average of 31% year to date through March 11. In comparison, the S&P 500 Index has fallen by 12% so far this year. The top-performing lab stocks thus far in 2022 have been Psychemedics, up 2%; Enzo Biochem, down 3%; and Myriad Genetics, down 5%. Labcorp is down 16% and Quest Diagnostics is off 21%.

Company (ticker)	Stock Price 3/11/22	Stock Price 12/31/21	2022 Price Change	Enterprise Value ($ millions)	Enterprise Value/Revenue	Enterprise Value/ EBITDA
Psychemedics (PMD)	$7.13	$7.02	2%	$43	1.8	17.0
Enzo Biochem (ENZ)	3.11	3.21	-3%	136	1.2	129.1
Myriad Genetics (MYGN)	26.12	27.60	-5%	1,843	2.7	NA
Castle Biosciences (CSTL)	39.95	42.87	-7%	694	7.4	NA
ProPhase Labs (PRPH)	6.65	7.17	-7%	95	2.4	NA
Labcorp (LH)	265.49	314.21	-16%	29,676	1.8	7.3
DermTech Inc. (DMTK)	13.01	15.80	-18%	171	14.4	NA
Exact Sciences (EXAS)	62.75	77.83	-19%	12,296	7.0	NA
Quest Diagnostics (DGX)	136.34	173.01	-21%	20,305	1.9	7.1
Sonic Healthcare (SHL.AX)*	33.18	46.63	-29%	18,532	2.0	7.7
CareDx (CDNA)	30.78	45.48	-32%	1,305	4.4	NA
Exagen (XGN)	7.84	11.63	-33%	48	1.0	NA
Opko Health (OPK)	3.12	4.81	-35%	2,246	1.3	31.9
Sema4 Holdings (SMFR)	2.84	4.46	-36%	257	1.2	NA
Veracyte (VCYT)	23.79	41.20	-42%	1,541	7.0	NA
Interpace Biosciences (IDXG)	4.25	$7.47	-43%	73	1.8	NA
Biocept (BIOC)	2.01	3.62	-44%	19	0.3	5.3
Aspira Women's Hlth (AWH)	0.97	1.77	-45%	67	10.5	NA
Guardant Health (GH)	54.40	100.02	-46%	5,982	16.0	NA
Fulgent Genetics (FLGT)	54.20	100.59	-46%	1,225	1.2	1.8
Invitae (NVTA)	7.26	15.27	-52%	2,337	5.1	NA
NeoGenomics (NEO)	15.89	34.12	-53%	2,068	4.3	NA
Biodesix (BDSX)	2.24	5.29	-58%	43	0.6	NA
Natera (NTRA)	38.98	93.39	-58%	3,204	5.1	NA
Unweighted Averages			-31%	$104,207	4.3	25.9

*Sonic Healthcare's figures are in Australian dollars

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

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THE DATA IS PRESENTED IN A USER-FRIENDLY EXCEL SPREADSHEET AND INCLUDES:

- National Provider Identifier (NPI)
- Provider Name
- Address
- Specialty (Breast, Cervix, Dermatology, FNA Biopsies, Gastro/Colorectal, Lung and Urology/Prostate)
- Specific Annual Medicare Biopsy Volume by CPT Code (2019)
- Overall Annual Biopsy Volume Estimates (2021)

CONDENSED SAMPLE DATA FOR GASTROENTEROLOGY-COLORECTAL BIOPSIES:

Provider Name	Address	City/State	Zip	Medicare Volume EGD Biopsy CPT 43239	Medicare Volume Sigmoidoscopy with biopsy CPT 45331	Medicare Volume Colonoscopy with Biopsy CPT 45380	Total Annual Medicare Biopsy Volume	Overall Annual Biopsy Volume Low Estimate	Overall Annual Biopsy Volume High Estimate
Wilmington Gastroenterology Endo Ctr	5115 Oleander Drive	Wilmington, NC	28403	789	76	1,081	1,946	5,838	9,730
Dearborn Surgery Center	18100 Oakwood Blvd	Dearborn, MI	48124	809	0	1,116	1,925	5,775	9,625
Medstar Medical Group - Southern Maryland LLC	24035 Three Notch Rd	Hollywood, MD	20636	1,048	0	865	1,913	5,739	9,565
Fresno CA Endoscopy ASC	7055 N Fresno St	Fresno, CA	93720	954	0	954	1,908	5,724	9,540
Alonzo Williams, MD	8908 Kanis Road	Little Rock, AR	72205	919	0	494	1,413	4,239	7,065
Nehme Gabriel, MD	822 Perkins St	Leesburg, FL	34748	714	12	538	1,264	3,792	6,320
Stephen Kirkpatrick, MD	3400 SE Frank Phillips Blvd	Bartlesville, OK	74006	607	0	532	1,139	3,417	5,695
Vinod Thakkar, MD	3581 S Highlands Ave	Sebring, FL	33870	588	0	534	1,122	3,366	5,610

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