

LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

Special New Year's Report: Lab Execs Share Outlook For 2022

For an inside look at what may be in store for the clinical lab industry this year, *Laboratory Economics* interviewed the top executives at a diverse group of 12 lab companies. Consensus trends identified include: 1) all execs report that Covid PCR test supplies have been adequate during the current testing surge; 2) rapid antigen tests for Covid are in short supply; 3) there is a critical shortage of lab employees (phlebotomists, couriers, front-end processors, MLT/MTs, etc.); and 4) growing recognition that digital pathology combined with artificial intelligence tools will soon transform the practice of pathology.

Continued on pages 3-9.

Sonic Buys ProPath

Sonic Healthcare (Sonic) acquired 100% of ProPath Services (Dallas, TX) for an undisclosed price on December 17, 2021. ProPath had been one of the largest pathologist-owned anatomic pathology labs in the nation. ProPath's annual revenue is approximately \$110 million. Its 500+ employees, including ~50 pathologists, serve roughly 1,000 physicians and 26 hospital clients across 45 states.

More details on page 10.

CDx Diagnostics Leads In Digital Pathology & AI

CDx Diagnostics (Suffern, NY), which specializes in esophageal precancer testing, is digitizing brush tissue slides and using its proprietary 3D imaging with AI neural net technology on the brush tissue acquired via endoscopy, in which specialty trained pathologists then interpret. In 2019, the American Society for Gastrointestinal Endoscopy (ASGE) updated their clinical guideline to include a recommendation for WATS^{3D}. In terms of sheer volume, Medicare data show that CDx processes more than 55,000 Part B claims for digital IHC (CPT 88361) per year—more than double the volume performed by any of the biggest national pathology lab companies (e.g., NeoGenomics, Quest/AmeriPath, etc.). See page 2 for *LE's* exclusive Q&A with Bill Huffnagle, Chief Executive of CDx.

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CDx Diagnostics Leads In Digital Pathology & AI (cont'd from page 1)

Can you provide some background information on CDx Diagnostics?

The company was founded in 1997 by Mark Rutenberg, PhD, a molecular biologist and electrical engineer, who invented CDx's proprietary technology, WATS^{3D}, for AI-assisted detection of precancerous esophagus cells from digitized cytopathology slides. CDx began marketing this technology to gastroenterologists and endoscopy centers in 2012.



Bill Huffnagle

I joined as CEO of CDx in 2019 as part of recapitalization in which the private equity firm Galen Partners became majority owner. Prior to joining CDx, I was President of the \$3 billion Reconstructive Division at Stryker Orthopaedics.

CDx operates a pathology laboratory in Suffern, New York, 30 miles north of Manhattan, and has approximately 160 employees, including 10 GI pathologists.

How does the WATS^{3D} test process work?

CDx supplies its patented cytology brush to endoscopy centers for use in upper endoscopies aimed at screening patients for Barrett's esophagus and dysplasia. Barrett's esophagus can arise from chronic acid reflux and increase your risk of developing esophageal cancer.

Our cytology brush obtains samples from a greater area of the esophagus than the traditional forceps biopsy. Two brush samples are collected and sent to our laboratory. One sample is prepared as a regular H&E slide, while the second is smeared on a slide and scanned into a digitized 3D whole slide image.

The digitized image is then analyzed using our AI algorithm to identify dysplastic aggregates hidden among normal esophageal tissue. The computerized cell images are highlighted and ranked according to their degree of atypicalities.

Our pathologists then review both the H&E slide at the microscope plus the digitized slide images by medical-grade computer monitor. They can focus their attention on those areas identified by our AI with the highest probability to be precancerous. The process helps our pathologists to quickly and more accurately find dysplastic cells that may otherwise have been hard to distinguish or missed completely.

RCTs have shown that esophageal precancers can be treated using radio frequency ablation, halting the progression of disease.

How accurate is WATS^{3D}?

To date 14 peer-reviewed published studies have shown a significant increase in added yield over forceps biopsies alone. Most recently, WATS^{3D} was shown to increase the yield of detection of dysplasia and intestinal metaplasia in both screening and surveillance in patients with Barrett's esophagus when used as an adjunct to traditional protocols (see *Clinical and Translational Gastroenterology* 2021;12:e00422). And, results of a multicenter, prospective, randomized trial demonstrated that the use of WATS^{3D} increased the detection of the most dangerous form of esophageal precancerous tissue by 4 times. (*Gastrointest Endosc* 2018;87(2):348-355). Finally, WATS^{3D} was included in the most recent American Society for Gastrointestinal Endoscopy Barrett's guideline as an adjunct to forceps biopsies.

Can the WATS^{3D} technology be applied to other cancers?

Yes. We are getting ready to start a prospective trial to detect the precursors of bile duct cancer. We are also performing proof-of-concept studies to use WATS^{3D} for stomach and colon cancers.

2022 Outlook For Labs: 12 Executive Perspectives *(cont'd from page 1)*

“Staffing has been and continues to be our biggest challenge,” according to **Jerry Hussong, MD**, Chief Executive of **Sonic Healthcare USA** (Austin, TX). The shortages are most acute at the preanalytical stage (accessioners and specimen processors) and for medical technologists.



*Jerry Hussong,
MD*

Sonic Healthcare USA is currently performing between 25,000 and 35,000 Covid PCR tests per day, a level equal to the volumes in August and September of 2021. Hussong says that positivity rates currently average from 10% to 40% depending on the region.

Aside from some minor freight and shipping delays over the holidays, Hussong says that supplies for Covid testing have been reliable. However, he has seen some intermittent shortages of supplies for non-Covid testing (e.g., tubes and needles).

Hussong believes Covid will wax and wane over time, but never be completely eradicated. “There will continue to be regional and seasonal outbreaks for years to come with the unvaccinated bearing the greatest risk.”

Lenco Diagnostic Laboratories (Brooklyn, NY) saw its positivity rates for Covid PCR testing rise from 5% in November to 11% in early December



*Robert Boorstein,
MD, PhD*

to a peak of 43% in late December, according to Medical Director **Robert Boorstein, MD, PhD**.

Lenco is currently performing an average of roughly 15,000 Covid PCR tests per day on nine Hologic Panther analyzers. About 5% to 10% of Lenco’s Covid PCR test volumes are combo tests that include either flu or respiratory syncytial virus (RSV). “We are seeing huge amounts of flu and RSV testing this year at much higher positive rates than any previous year.”

Boorstein says that test supplies have not been a choke point. A bigger concern is overworked staff

who are being asked to work additional shifts/overtime. “We’re doing twice as much volume with the same staff.” Lenco has 350 employees.

“This is a humbling disease. No one predicted this surge and there seems to be no rhyme or reason to where and when it spreads,” notes Boorstein.

As to when the pandemic might end, Boorstein says, “Predictions in this space have a very short half-life. I see no real evidence of seasonality. For example, Australia is currently experiencing record positivity during their summer season.”

On the bright side, Boorstein notes that “The current increase in infections is so rapid that it can’t be sustained that much longer as everyone will have gotten Covid....Some experts are predicting Covid might peak in January. That seems reasonable.” He notes that positivity rates at Lenco declined to roughly 30% in mid-January.

As for the huge PCR testing capacity that has been built up, Boorstein says that “Ultimately some equipment will be repurposed (e.g., aliquoters). But we may have to decommission some equipment. There are no current clinical needs that can sop up the capacity that labs now have.”

“The pandemic has had a definite impact on our workforce, but we have managed to keep up with the demand for testing. This is sort of the new normal. At any given time, we have multiple patient service centers that we have to close because of worker shortages,” according to **Dave Dexter**, President and CEO of **Sonora Quest Laboratories** (SQL-Phoenix, AZ).



Dave Dexter

As of early January 2022, SQL, a joint venture between Banner Health and Quest Diagnostics, was conducting 30,000 Covid tests per day, with plans to ramp up to 37,000 tests per day by mid-January. “Our positivity rate is at 37% right now, the highest it has ever been, and I wouldn’t be surprised to see it hit 45% or more,” says Dexter. He

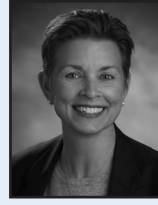
says SQL plans to keep capacity high even once the current Covid surge dies down as part of Operation Catapult. The lab operates five Hologic Panthers, three Roche 8800s and will soon begin operating all eight Perkin Elmer lines/instruments.

SQL moved into a new 250,000 square foot core lab in spring 2020 and is in the process of implementing a six-year plan focused on innovation and precision medicine. “We have tremendous opportunities in 2022,” says Dexter.

A major initiative for the coming year is to move for-profit SQL and Banner Health’s non-profit Laboratory Sciences of Arizona (LSA) completely to digital pathology. LSA manages 30 hospital labs in six states, and SQL and LSA together manage 65 CLIA licensed labs and several small COLA labs as part of its integrated laboratory network. SQL contracts with seven major pathology groups with about 130 pathologists, both commercial and academic, and has partnerships with the University of Arizona Cancer Center and BannerMD Anderson. SQL is working with Paige, an artificial intelligence software company, to enhance its digital pathology offerings.

“We are in transition right now with the initial focus on Arizona,” explains Dexter. “It will be a big workflow change for pathologists. Many of them were very reticent to give up their microscopes, but they have enthusiastically embraced the Phillips digital pathology platform, and I expect it to be a game changer.”

Despite spending a great deal of time and effort on COVID testing, **ACL Laboratories** (West Allis, WI), which serves 27 hospitals in the Advocate Aurora Health Care System in Illinois and Wisconsin, is also planning for improvements in the laboratory, including automation in microbiology, expansion of its genetic testing menu, increased support of pain management and decentralization of lab testing, according to ACL President **Barbara Bigler**.



Barbara Bigler

“We accept that management of the pandemic is the priority,” says Bigler. “Where possible, we are moving the organization forward at a pace we can absorb.”

Among the genetic tests that ACL plans to introduce in the coming year are a 139-mutation Cystic Fibrosis Panel and a Myeloid panel, which includes 74 genes targeting disorders Acute Myeloid Leukemia, Myelodysplastic Syndromes and Myeloproliferative Neoplasm. In addition, ACL will be decentralizing blood cultures to each hospital and adding molecular instrumentation for identification of positive blood cultures to aid in faster diagnosis and treatment.

As of early January, ACL Laboratories was running an average of 7,000 Covid tests per day, the most it has conducted since the beginning of the pandemic. The Omicron surge has placed a great deal of stress on the hospitals in the health system, with several of them near capacity. More than 80% of those being hospitalized with Covid are unvaccinated, notes Bigler.

One of the challenges that ACL faces is workforce shortages, especially for phlebotomists. ACL has increased its minimum wage to \$18 and is offering sign-on and referral bonuses to attract more workers for nearly all clinical-related positions, according to Bigler.

Aegis Sciences Corp. (Nashville, TN) has performed more than 10 million Covid PCR tests to date, according to Chief Executive **Frank Basile, MD**. As of mid-January, Aegis was performing more than 30,000 Covid PCR tests per day with the capacity for up to 60,000 daily tests. Aegis provides Covid PCR tests nationwide through a partnership with Walgreens. Covid positivity rates at Aegis are currently averaging 36%.



*Frank Basile,
MD*

Basile says the supply chain for Covid PCR testing is holding up well despite the current surge in demand.

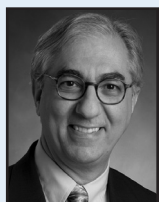
Like many, Basile had thought that the introduction of Covid vaccines in early 2021 would have put the pandemic “in the rear-view mirror by now.” “I thought that 90% to 95% of the U.S. population would get vaccinated and I’ve been surprised by the hesitancy of some.”

Aegis has approximately 1,200 employees and the majority have been vaccinated. “We’re actively encouraging people to get vaccinated.” Efforts have included busing employees to vaccination centers, according to Basile.

Aegis, which is the nation’s largest independent toxicology testing lab, has recently seen its toxicology test volumes exceed pre-pandemic levels. Basile attributes the growth to test menu expansion, including: 1) BioDetect, which enables a higher level of specimen integrity to deal with the rise of synthetic urine; 2) new tests for novel psychoactives such as synthetic fentanyl and benzodiazepine; and 3) expanded oral fluid test menu—an area that is rapidly expanding especially with telehealth.

Aegis recently expanded its test menu to include PCR-based tests for respiratory infection test panels, urinary tract infections, sexually-transmitted diseases and gastrointestinal diseases. Basile says Aegis may add additional PCR-based tests in 2022.

The clinical laboratory at the **University of Texas Medical Branch (UTMB)** in Galveston is close to launching a new high-throughput Covid neutralizing antibody test that could help individuals determine if the amount of neutralizing antibody levels predict immune status for primary and breakthrough infections, according to **Michael Laposata, MD, PhD**, Professor and



*Michael Laposata,
MD, PhD*

Chairman of the Department of Pathology.

While there are multiple neutralizing antibody tests available clinically and for investigative purposes, none can be done in the numbers Laposata hopes to per-

form. “Our goal is to perform as many as 1,000 tests per day with automation,” he says. UTMB scientists, notably Dr. Pei-Yong Shi, used the antibody test to assess the efficacy of vaccines from Pfizer and BioNTech. “We’re in a unique position here because we already have a neutralizing antibody test validated for the vaccine trials,” says Laposata.

UTMB plans to not only provide results for all Covid related tests, but also to continue to provide patient-specific, expert-driven and constantly updated comments that can be used by physicians to determine whether an individual is infected and has shown an immune response. “To my knowledge, we are the only lab that provides a patient specific interpretation along with the Covid-19 results for every case, and this has had a major effect on patient outcome in our institution,” says Laposata.

UTMB has been running around 15,000 Covid tests per week in the last few weeks, with a positivity rate of more than 40%. It is too soon to tell if Covid testing will drop off as the year progresses, notes Laposata. “If modification of the vaccine by Pfizer expected to be more directed toward the Omicron variant (presumably available in March) is successful, and people actually take the vaccine, I think testing will decrease because there will be fewer people with infections causing mild symptoms in the nasopharyngeal region,” he says. “We have to get past the point where every scratchy throat has to include coronavirus infection in the differential diagnosis to really reduce the testing need.”

In addition to advancing the Covid-19 diagnostic management team (DMT) with the new neutralizing antibody test, the UTMB lab also is planning this year to launch several new DMTs focused on pharmacogenomics, anemia and oncology screening – this in addition to the six other DMTs UTMB already has. These teams are designed to offer healthcare professionals assistance in selecting appropriate diagnostic tests and interpreting results for individual patients.

OPKO Health's BioReference Laboratories (Elmwood Park, NJ) is currently performing a daily average of between 30,000 and 50,000 Covid tests, including both PCR and rapid antigen tests, according to **Jon Cohen, MD**, Executive Chair-



Jon Cohen, MD

man of BioReference. "There's no sign yet that cases are peaking."

Cohen says that the supply chain for Covid PCR tests is holding up well, but rapid antigen tests are harder to find. However, the

biggest challenge is finding and hiring employees, especially medical technologists, molecular testing staff and specimen accessioners.

Cohen says that BioReference's Scarlet Health is growing quickly. Scarlet Health allows patients to schedule specimen collection for Covid PCR and other tests digitally. Phlebotomists come to the patient's home or office to collect their test specimen, which is then sent to BioReference for testing. MVP Health Care (Schenectady, NY), which covers 700,000 members across New York and Vermont, recently agreed to offer the Scarlet Health service.

BioReference is also seeking more lab management service agreements with hospitals. The company's biggest contract to date (announced May 2020) is with Westchester Medical Center Health Network (WMCHHealth). WMCHHealth is a 10-hospital 1,700-bed healthcare system headquartered in Valhalla, New York. BioReference provides inpatient lab administrative services, reference testing and outreach testing services.

"The transition to digital pathology combined with artificial intelligence is going to happen faster than you think," says **Nicolas Cacciabeve, MD**, Managing Member at



Nicolas Cacciabeve, MD

Advanced Pathology Associates (Rockville, MD). "I'm convinced it will improve pathologists' precision and accuracy and it's the safest way to address the growing shortage of pathologists."

Advanced Pathology Associates (APA) has 20 employees, including 10 pathologists and four pathologists' assistants. The group provides medical director and lab management services to three Adventist Healthcare hospitals and their central anatomic pathology reference lab, Capital Choice Pathology Lab (CCPLab), two hospitals in the University of Maryland Healthcare System as well as three independent molecular labs.

Cacciabeve was principal investigator and five APA pathologists were listed as authors in the landmark study "Whole Slide Imaging Versus Microscopy for Primary Diagnosis in Surgical Pathology," published in the *American Journal of Surgical Pathology*. The FDA relied on this study when it cleared the Philips IntelliSite digital pathology system for primary clinical diagnostic use in April 2017.

Cacciabeve says that two of APA's pathologists are currently in the process of validating the use of digitized whole-slide images for primary diagnosis sign out. The validation process includes sending each pathologist digitized images for 100 cases that they had previously interpreted by traditional microscope. Cacciabeve then compares the diagnoses with the expectation of a 96% concordance or better. "If I feel there needs to be more cases pulled either in a certain diagnostic or organ category, I can extend the validation," notes Cacciabeve. He anticipates that all 10 APA pathologists will be validated and switch to using digital pathology for the great majority of their cases within the next three to six months. Slide digitization is performed at CCPLab using scanners from Philips and Roche-Ventana.

Cacciabeve is also eager to add artificial intelligence tools. Initially, APA plans to evaluate Ibex's algorithm for breast cancer for quality assurance. Pathologists will interpret breast cancer cases via digital pathology and then those same cases will be reread using Ibex's AI. Any cases where there is a discrepancy between the pathologist and the AI will be reviewed by another pathologist.

Over time, Cacciabeve says that AI will be used as an initial screening tool that identifies hot spots for pathologists to focus their attention. He believes that AI has the potential to increase pathologist productivity by 30% or more.

Separately, Cacciabeve says that Covid PCR test volumes at the Adventist labs have more than doubled as of late December compared with a month earlier. The supply chain is holding up. The more pressing concern is a critical shortage of lab employees. “We’re backing away from testing healthy asymptomatic patients for Covid and asking our hospital physicians to be really careful before ordering non-essential testing.”

Jim Sweeney, President of the **PathAI Diagnostic Division** (Memphis, TN), says his lab was performing roughly 5,000 to 6,000 Covid PCR tests per day in late December. “The rate of ascent



Jim Sweeney

in test volume has been a straight line up and has already passed previous highs reached in September. We’re hoping it may decline as fast as it has risen.”

PathAI, which develops artificial intelligence software tools for pathologists, formed its diagnostics division through the acquisition of Poplar Healthcare in August 2021 (see *LE*, August 2021).

Sweeney says that the PathAI lab operates a drive-thru testing site from its parking lot that is performing between 2,000 and 2,500 Covid PCR tests per day for symptomatic patients. Positivity rates averaged 30% in late December.

The PathAI lab is also performing about 4,000 to 4,500 Covid PCR screening tests per day for schools, universities and municipalities. Positivity rates averaged less than 1% in late December.

The PathAI lab primarily uses Roche cobas and Hologic Panther analyzers for Covid PCR testing. Sweeney says the supply chain is currently holding up well with no shortages of Covid test kits, viral transport media or swabs.

The PathAI lab has 350 employees, including 25 pathologists. Sweeney says that the lab has been able to deploy its workforce back and forth from its traditional anatomic pathology testing to Covid PCR testing as each new wave has peaked and bottomed without experiencing staffing shortages.

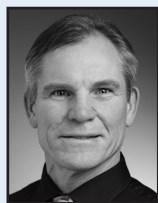
Separately, Sweeney says that the sale to PathAI has accelerated Poplar Healthcare’s transition to digital pathology, which started about two years ago. Roughly 10% to 15% of the lab’s pathology cases are now being digitized. Digital pathology is primarily being used to serve TC-PC clients, where the PathAI lab prepares slides and sends digitized images to pathology clients for interpretation.

In addition, the PathAI lab has built out a biopharmaceutical research lab that provides digitized slides to biopharma firms for use in clinical trials.

This year, Sweeney says that the PathAI lab will begin implementing AI-based tools for uropathology, GI pathology and dermatopathology.

Wisconsin Diagnostic Laboratories

(Milwaukee) is currently performing about 1,000 to 1,500 Covid PCR tests per day, representing about 20% to 30% of its total volumes, according to Executive Director **Michael Baron**. WDL’s current positivity rate for Covid is about 13%, a rate similar to what it saw during peak periods last year. WDL has now performed more than one million Covid PCR tests to date.



Michael Baron

WDL, which is owned by Froedtert Health System, serves more than 40 hospitals, 900 long-term care facilities and 200 physician practices in Wisconsin and Northern Illinois. The lab has about 450 employees and contracts with 40 pathologists associated with the Medical College of Wisconsin.

Baron says that WDL saw a surge in RSV positivity rates in October that approached 15%, but have since fallen to just under 5%. Similarly, he says that flu cases went up and have now started coming down.

Baron says that WDL uses multiple PCR testing platforms (e.g., TaqPath, Roche Cobas, Cepheid and Biofire) and is not currently experiencing any supply shortages.

“We are having a difficult time finding MTs/MLTs and we are seeing more churn with the younger generation worker,” notes Baron. “I have been working on alternative methods of bringing in staff, such as training non-certified techs, and WDL is the first lab in the state in developing an apprentice program with DWD [Wisconsin Department of Workforce Development]. It’s a real opportunity for people coming out of college with a science degree to train on the job, gain classroom instruction, and then get ASCP-certified.

It is a non-traditional training program—right now we have about eight people in the program. This coming spring, we expect to start the apprenticeship program with two apprentices.”

Quantum Pathology (Waltham, MA) chose to stick with its core anatomic pathology business (uropathology, GI pathology, dermatopathology and podiatric pathology) and never got into Covid PCR testing, according to President and CEO **Erik DiGuilio**. Case volumes plummeted as a result of lockdowns in the spring of 2020, but have since rebounded and are currently running at more than 50% above pre-pandemic levels. DiGuilio says the growth has been fueled by existing physician clients that have referred Quantum to other new clients.



Erik DiGuilio

DiGuilio attributes the client loyalty to Quantum’s responsiveness to special requests. For example, he says that often a specialist will ask for quick turnaround time on a particular patient case they

are worried about. Quantum will prioritize these cases and get the report to the ordering physician within 24 hours. DiGuilio handles many client requests directly. His wife and sister are also key members of Quantum’s sales and service team.

DiGuilio founded Quantum in June 2014 after waiting out a non-compete agreement from his six years as Vice President of Sales and Marketing at Strata Pathology Services. Quantum currently has 55 employees, including 10 pathologists, and processes roughly 80,000 patient cases per year which translates to 120,000 specimens per year.

The majority of Quantum’s clients are in the New England region (CT, MA, ME, NH, VT and RI). DiGuilio says the biggest challenge to expanding geographically is gaining access to in-network insurance contracts.

American Health Associates (AHA-Miramar, FL) is currently performing its highest volume of Covid PCR tests as at any point in the pandemic, but is not experiencing any supply bottlenecks,



Chris Martin

according to President **Chris Martin**.

Martin says that the far bigger challenge is finding employees, especially for customer service, phlebotomy, front-end specimen processing and medical technologists. “The cost of living keeps getting higher and employees are worried about having their wages keep up.”

AHA is an independent laboratory that operates 16 regional labs and serves more than 4,000 nursing homes and assisted-living facilities throughout the Southeast, Midwest, and Mid-Atlantic. Its biggest markets are Ohio, Florida, Kentucky, Michigan and Tennessee.

Martin says that AHA will open a new laboratory near Boston within the next few months for a northeast expansion driven by client demand.

Top 25 Hospital-Owned Independent Labs

Medicare Part B carrier allowed payment data from CMS shows that the top 25 hospital-owned labs (with their own National Provider Identifier (NPI) number) grew their Part B revenue from \$247 million in 2016 to \$251 million in 2019—an annual growth rate of 0.6%. The fastest-growing hospital-owned lab was UCLA Outreach Clinical Lab, which grew from \$3.1 million to \$5.5 million—an annual growth rate of 21.6%.

Top 25 Hospital-Owned Independent Labs & Joint Ventures

Laboratory Name	Owner	Location	Total Medicare Allowed Payment 2019	Total Medicare Allowed Payment 2016	3-Year CAGR % Chg
Sonora Quest Laboratories	Banner Health and Quest Diagnostics	Phoenix, AZ	\$56,862,431	\$56,816,088	0.0%
Northwell Health Laboratories	Northwell Health	New Hyde Park, NY	24,179,004	19,613,683	7.2%
ACL Laboratories	Advocate Aurora Health	West Allis, WI	21,323,489	22,541,261	-1.8%
Diagnostic Laboratory of OK	Integrus Health and Quest Diagnostics	Oklahoma City, OK	13,347,173	13,118,950	0.6%
Regional Medical Laboratory, Inc	St. John Health System	Tulsa, OK	12,809,554	12,402,270	1.1%
HNL Lab Medicine	Lehigh Valley Health Network	Allentown, PA	12,659,859	12,061,437	1.6%
Diagnostic Laboratory Services	The Queen's health System	Aiea, HI	9,989,845	9,881,962	0.4%
Pacific Diagnostic Laboratories	Cottage Health	Santa Barbara, CA	8,426,376	8,225,608	0.8%
Quest Diagnostics UPMC JV	UPMC and Quest Diagnostics	Pittsburgh, PA	7,601,298	7,015,716	2.7%
Scripps Health	Scripps Health	San Diego, CA	7,128,409	7,460,942	-1.5%
Compunet Clinical Labs	Premier Health and Valley Pathologists	Moraine, OH	7,120,040	7,960,182	-3.6%
Tricore Reference Labs	Univ. of NM Health Sys. and Presbyterian Health	Albuquerque, NM	6,967,113	6,934,429	0.2%
Professional Clinical Labs (dba Alverno Labs)	Franciscan Alliance and AMITA Health	Hammond, IN	6,926,367	6,367,125	2.8%
Mayo Clinic Jacksonville	Mayo Clinic	Jacksonville, FL	6,583,852	5,279,208	7.6%
UCLA Outreach Clinical Lab	Regents of the Univ. of California	Panorama City, CA	5,502,064	3,063,360	21.6%
Univ. Hospitals Lab Services Fdn.	Univ. Hospitals of Cleveland	Cleveland, OH	5,258,313	5,197,465	0.4%
Saint Francis Outreach Services	St. Francis Health System	Tulsa, OK	5,177,050	4,904,857	1.8%
Associated Clinical Laboratories	Local hospitals and Quest Diagnostics	Erie, PA	4,733,150	5,260,464	-3.5%
Texas Health Physicians Group	Texas Health	Euless, TX	4,573,912	5,835,666	-7.8%
Mayo Collaborative Services	Mayo Clinic	Rochester, MN	4,534,676	3,490,290	9.1%
ACM Medical Laboratory	Rochester Regional Health	Rochester, NY	4,396,298	2,578,269	19.5%
Marshfield Clinic	Marshfield Clinic Health Sys.	Marshfield, WI	4,062,380	10,380,795	-26.9%
Nordx	Maine Health	Scarborough, ME	3,944,758	4,137,619	-1.6%
Legacy Laboratory Services	Legacy Health	Portland, OR	3,911,358	3,303,951	5.8%
Cotton-O'Neil Clinic Rev. Trust	Stormont Vail Health	Topeka, KS	3,798,616	3,587,920	1.9%
Total for 25 Hospital-Owned Labs			\$251,817,385	\$247,419,517	0.6%
Grand Total for All 2,800 Independent Labs			\$5,808,100,308	\$4,806,415,863	6.5%

Source: *Laboratory Economics* from Medicare Provider Payment Data from CMS for 2016-2019

Sonic Buys ProPath *(cont'd from page 1)*

ProPath was established as an anatomic pathology practice in 1966. Growth has been almost entirely organic, including the expansion into clinical laboratory services in 2017. In early 2020 ProPath acquired New England Tissue Issue, an AP company located in Massachusetts.

ProPath's pathologists will join as colleagues with Sonic's existing group of 330 pathologists in the US. ProPath's leadership team, including Chairman and CEO Cory Roberts, MD, are expected to hold senior roles at Sonic Healthcare USA.

The acquisition of ProPath follows Sonic's purchase of Aurora Diagnostics for \$540 million in January 2019.

Coker Capital (Charlotte, NC) served as a financial advisor to ProPath, while Haynes and Boone LLP (Dallas, TX) provided legal services.

Progenity Sells Lab Business To Northwest Pathology

Progenity Inc. (San Diego, CA) has sold its lab business, Avero Diagnostics (Irving, TX), to Northwest Pathology (Bellingham, WA) for \$10.9 million in cash. The sale of Avero Diagnostics is expected to reduce Progenity's annual operating expenses by approximately \$28 million. Progenity now expects to focus on its research and development efforts for new drugs and diagnostic tests.

Avero Diagnostics (aka Mattison Pathology, LLP) performs anatomic, genetic and Covid tests at CLIA-certified labs in Lubbock and Irving, Texas. Annual revenue is approximately \$40 million. Avero was originally founded by Tom Mattison, MD, and Trae Mattison, MD, in 2004, and then sold to Progenity in 2015.

Northwest Pathology, which employs 10 pathologists, operates a full-service lab and provides pathology services to 13 hospitals and more than 100 outpatient clinics in Washington and Alaska.

Labcorp To Buy PGDx For \$575 Million

Labcorp (Burlington, NC) has agreed to acquire Personal Genome Diagnostics Inc. (PGDx-Baltimore, MD) for \$450 million in cash at closing plus up to an additional \$125 million based on future performance milestones. The transaction is expected to close in the first half of 2022.

PGDx was founded in 2010 by two cancer scientists, Luis Diaz, MD, and Victor Velculescu, MD, PhD, from Johns Hopkins University. The company received FDA clearance to market its comprehensive tumor profiling test kit, PGDx ELIO tissue complete, in May 2020. The test analyzes 505 genes from FFPE tissue samples from advanced cancer patients to inform treatment decisions for 35 solid tumor types. PGDx ELIO is covered by Medicare under the PLA code 0250U at a rate of \$2,920.

PGDx, which has 114 employees, recorded revenue of approximately \$22 million in 2021. Revenue is expected to grow nearly 82% to \$40 million in 2022. Labcorp expects the acquisition of PGDx to negatively impact its earnings slightly over the next couple of years, but provide returns in excess of the cost of capital by year five.

PGDx had raised more than \$200 million from outside investors, including New Enterprise Associates, Bristol-Myers Squibb and Cowen Healthcare Investments.

Exact Sciences Acquires PreventionGenetics For \$190 Million

Exact Sciences (Madison, WI) paid \$190 million, including 50% in Exact common stock and 50% in cash, for PreventionGenetics (Marshfield, WI) in early January. PreventionGenetics operates a CLIA-certified lab that performs proprietary next-gen sequencing tests, including PGnome Health Screen (list price \$2,290) and PGxome Prenatal (list price \$2,860).

U.S. Laboratory Acquisition Summary for 2021

More than \$2.4 billion of lab acquisitions were completed at an average purchase price/annual revenue multiple of 2.8x, according to an exclusive analysis conducted by *Laboratory Economics*.

Labs developing next-gen sequencing tests and liquid biopsies obtained the highest valuations. For example, Labcorp is paying 14.4x annual revenue for its pending acquisition of Personal Genome Diagnostics, Exact Sciences paid 5.3x for PreventionGenetics, Veracyte paid 10.7x for HalioDx and 14.9x for Decipher Biosciences, and Bio-Techne Corp. paid 10.7x for Asuragen.

Excluding those high-priced deals, the average multiple paid for traditional clinical and anatomic pathology labs was a more down-to-earth 1.6x in 2021.

U.S. Laboratory Acquisition Summary for 2021 (\$ millions)

Date	Buyer	Target	Purchase Price*	Acquired Revenue	Price/Revenue
Pending	Labcorp	Personal Genome Diagnostics (Baltimore, MD)	\$575	\$40	14.4
Jan-22	Exact Sciences	PreventionGenetics (Marshfield, WI)	190	36	5.3
Dec-21	Sonic Healthcare	ProPath (Dallas, TX)	NA	110	NA
Dec-21	Northwest Pathology	Progenity's Avero Diagnostics (Irving, TX)	10.9	40	0.3
Dec-21	Castle Biosciences	Cernostics (Pittsburgh, PA)	80	NA	NA
Dec-21	Quest Diagnostics	Labtech Diagnostics (Anderson, SC)	NA	NA	NA
Nov-21	EKF Diagnostics	Advanced Diagnostic Laboratory (San Antonio, TX)	10	12	0.8
Sep-21	Labcorp	Myriad's Vectra autoimmune testing business (Salt Lake City, UT)	150	35	4.3
Aug-21	Fulgent Genetics	CSI Laboratories (Alpharetta, GA)	52	43E	1.2
Aug-21	ProPhase Labs	Nebula Genomics (San Francisco, CA)	14.6	NA	NA
Aug-21	PathGroup	DermLab (Birmingham, AL)	NA	NA	NA
Aug-21	OPKO/BioReference	Roche's Ariosa U.S. prenatal testing business	NA	NA	NA
Aug-21	Quest Diagnostics	Nationwide Laboratory Services (Boca Raton, FL)	26	NA	NA
Aug-21	Veracyte Inc.	HalioDx (Marseille, France and Richmond, VA)	321	30	10.7
Jul-21	Eurofins Scientific	DNA Diagnostics Center (Fairfield, OH)	NA	55	NA
Jul-21	Labcorp	OmniSeq (Buffalo, NY)	NA	NA	NA
Jul-21	PathAI	Poplar Healthcare (Memphis, TN)	NA	NA	NA
Jun-21	Apollo Medical Holdings	Sun Clinical Laboratories (El Monte, CA)	4	NA	NA
Jun-21	PathGroup	Skin Diagnostics Group (Birmingham, AL)	NA	NA	NA
Jun-21	Quest Diagnostics	Mercy Health clinical lab outreach (AR, KS, MO, OK)	225	NA	NA
May-21	Castle Biosciences	Myriad's MyPath Laboratory (Salt Lake City, UT)	32.5	10E	3.3
Apr-21	Augustus Labs	Evergreen-Sheridan Laboratories (Palos Heights, IL)	NA	NA	NA
Apr-21	DiamiR	Interpace Biosciences (Connecticut lab)	NA	NA	NA
Mar-21	Veracyte Inc.	Decipher Biosciences (San Diego, CA)	595	40	14.9
Mar-21	Bio-Techne Corp.	Asuragen (Austin, TX)	320	30	10.7
Mar-21	C2i Genomics	QNA Dx (Cambridge, MA)	NA	NA	NA
Jan-21	ChristianaCare	Delaware Clinical & Laboratory Physicians (Newark, DE)	NA	NA	NA
Totals & Weighted Average**		(all lab deals completed in 2021)	\$2,429	\$855	2.8
Totals & Weighted Average		(excluding next-gen and liquid biopsy labs)	\$1,193	\$755	1.6

*Purchase price includes upfront cash paid plus contingent consideration

**Excludes Labcorp's pending purchase of Personal Genome Diagnostics and Exact Sciences acquisition of PreventionGenetics in January 2022

Source: *Laboratory Economics*

Lab Stocks Fell 2% In 2021

Twenty-three lab stocks fell by an unweighted average of 2% in 2021. Overall, nine lab stocks rose and 14 fell. The top-performing lab stocks in 2021 were Interpace Biosciences, up 138%; Fulgent Genetics, up 93%; and LabCorp, up 54%. Quest Diagnostics was up by 45% (total return with dividends was 48%) and Sonic Healthcare was also up by 45% (total return was 48%). In comparison, the S&P 500 Index rose by 27% last year (total return was 29%).

Company (ticker)	Stock Price 12/31/21	Stock Price 12/31/20	2021 Price Change	Enterprise Value (\$ millions)	Enterprise Value/Revenue	Enterprise Value/EBITDA
Interpace Biosciences (IDXG)	\$7.47	\$3.14	138%	\$87	2.2	NA
Fulgent Genetics (FLGT)	100.59	52.10	93%	2,567	2.5	3.3
Labcorp (LH)	314.21	203.55	54%	34,371	2.1	7.4
Quest Diagnostics (DGX)	173.01	119.17	45%	25,006	2.3	8.0
Sonic Healthcare (SHL.AX)*	46.63	32.15	45%	24,741	2.8	11.5
Myriad Genetics (MYGN)	27.60	19.77	40%	1,931	2.7	NA
Psychemedics (PMD)	7.02	5.09	38%	43	1.8	16.8
Enzo Biochem (ENZ)	3.21	2.52	27%	141	1.2	133.7
Opko Health (OPK)	4.81	3.95	22%	3,373	1.8	18.9
Natera (NTRA)	93.39	99.52	-6%	8,196	14.5	NA
Exagen (XGN)	11.63	13.20	-12%	109	2.3	NA
Veracyte (VCYT)	41.20	48.94	-16%	2,778	14.9	NA
Biocept (BIOC)	3.62	4.44	-18%	46	0.7	9.9
Guardant Health (GH)	100.02	128.88	-22%	10,100	29.4	NA
Castle Biosciences (CSTL)	42.87	67.15	-36%	721	8.4	NA
NeoGenomics (NEO)	34.12	53.84	-37%	4,271	8.8	NA
CareDx (CDNA)	45.48	72.45	-37%	2,060	7.5	NA
Exact Sciences (EXAS)	77.83	132.49	-41%	14,596	8.3	NA
DermTech Inc. (DMTK)	15.80	32.44	-51%	228	21.2	NA
Progenity (PROG)	2.09	5.31	-61%	446	5.9	NA
Invitae (NVTA)	15.27	41.81	-63%	3,932	9.0	NA
Aspira Women's Hlth (AWH)	1.77	6.71	-74%	157	24.5	NA
Biodesix (BDSX)	5.29	20.16	-74%	125	1.7	NA
Unweighted Averages			-2%	\$140,026	7.7	26.2

*Sonic Healthcare's figures are in Australian dollars

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

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