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Competitive Market Analysis For Laboratory Management Decision Makers

The Light At The End Of The Pandemic Tunnel

Tremendous progress has been made since the apparent U.S. peak in the pandemic in early January. A combination of naturally-acquired immunity and vaccinations have joined to dramatically lower daily Covid-19 PCR test volume demand (-43%), confirmed cases (-72%), hospitalizations (-67%) and deaths (-79%) in the United States. *More stats on pages 13-14*.

Pandemic Data Tracking			
7-Day Averages	Early January 2021 Peaks	Mid-April 2021	Percent Change
Covid PCR Tests	2,036,044	1,152,186	-43%
Confirmed Covid Cases	249,861	69,577	-72%
New Hospital Admits	16,521	5,507	-67%
Covid Deaths	3,457	712	-79%
Source: CDC			

Huge Government Contracts For Covid Testing At Schools To Be Awarded Soon

n April 27, the Department of Health and Human Services (HHS) is scheduled to announce the winners of four regional contracts to coordinate Covid-19 PCR and rapid antigen testing at schools (K-8th grade) and homeless shelters.

Each of the four regional winners will organize the distribution of testing supplies and contract with labs across the country to collect specimens, perform tests, and report results to public health agencies (within 48 hours). Each regional coordinator is expected to manage a total of 1.5 million or more tests per week over a six-month period. *Continued on page 6*.

New Price Transparency Law Reveals Big Variations In Hospital Lab Rates

On January 1, U.S. hospitals were required to start posting the discounted prices they negotiate with insurers from routine lab tests to complex heart surgery and everything between. An exclusive analysis of the new data by *Laboratory Economics* has revealed tremendous variation in rates for the basic metabolic panel—a routine high-volume clinical lab test that has a Medicare CLFS rate of \$8.46. In California, for example, a sample of 10 hospitals showed negotiated rates as low as \$5.82 for the test and as high as \$559.55—nearly a one-hundred-fold difference!

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NEW PRICE TRANSPARENCY LAW REVEALS BIG VARIATIONS (cont'd from p. 1)

The new federal regulations require hospital websites to provide a consumer-friendly way to examine the prices of 300 "shoppable" services, including at least 14 high-volume clinical lab tests.

Hospitals are required to display:

- **Discounted cash price:** the charge that applies to an individual who pays cash for the shoppable service.
- Minimum negotiated rate: the lowest charge that a hospital has negotiated with all third-party payers for the shoppable service.
- Maximum negotiated rate: the highest charge that a hospital has negotiated with all third-party payers for the shoppable service.
- Payer-specific negotiated rate: the charge that a hospital has negotiated with a third-party payer for the shoppable service.

CMS says that it will audit a sample of hospitals for compliance, in addition to investigating complaints. Hospitals may face civil monetary penalties for noncompliance.

The majority of hospitals have yet to unveil the data, despite the January 1 deadline and a potential fine of \$300 per day for noncompliance. Apparently, some hospitals may choose to risk being fined up to \$109,500 for a year of noncompliance rather than go through the tedious process of collecting and posting their payer rates. However, approximately 1,700 hospitals have posted their negotiated rates and more are expected to do so in the coming weeks.

Laboratory Economics examined New York City-area hospital rates for the basic metabolic panel (CPT 80048), which is currently reimbursed by the Medicare CLFS at \$8.46.

Negotiated Hospital Rates for Basic Metabolic Panel/CPT 80048 in New York City Area

		Discounted	Minimum	Maximum	Aetna	Cigna	United-
	Staffed	Cash	Negotiated	Negotiated	Com-	Commer-	Health
Hospital Name	Beds	Price	Rate	Rate	mercial	cial	Commercial
Ellenville Regional Hospital (Ellenville, NY)	25	\$35.25	\$21.62	\$37.84	\$30.55	\$35.25	\$35.25
Greenwich Hospital (Greenwich, CT)	181	56.55	36.77	46.53	37.22	39.05	46.53
Jamaica Hospital (Richmond Hill, NY)	588	35.00	7.25	35.00	9.05	21.94	11.91
Morristown Medical Center (Morristown, NJ)	669	\$125.00	\$7.61	\$106.25	\$9.14	\$11.75	\$8.46
NYC Health-Bellevue Hospital (New York, NY)	912	8.93	8.46	15.62	15.62	NA	NA
NY Presbyterian/Weill Cornell (New York, NY)	2,670	102.30	33.72	102.30	102.30	52.15	NA
St. Mary's General Hospital (Passaic, NJ)	145	8.46	6.92	54.88	16.92	16.59	6.92
University Hospital (Newark, NJ)	367	9.73	9.30	22.59	22.42	17.10	17.00
Waterbury Hospital (Waterbury, CT)	243	154.43	8.47	81.99	15.69	26.49	77.52
Yale-New Haven Hospital (New Haven, CT)	1,549	56.55	41.77	51.48	45.68	47.57	48.87
Unweighted Averages	735	\$59.22	\$18.19	\$55.45	\$30.46	\$29.77	\$31.56

Source: Laboratory Economics from each hospital/price transparency/shoppable service files

Among 10 NYC-area hospitals analyzed, the discounted cash rate offered to self-paying customers for the basic metabolic panel ranged from a low of \$8.46 at St. Mary's General Hospital (Passaic, NJ) to a high of \$154.43 at Waterbury Hospital (Waterbury, CT).

St. Mary's General Hospital also had the lowest negotiated commercial insurance rate for the basic metabolic panel (\$6.92 from UnitedHealthcare). Morristown Medical Center (Morristown, NJ) had the highest negotiated commercial insurance rate (\$106.25 paid by Consumer Healthcare Network (CHN)).

California Hospital Lab Test Rates

Among 10 California hospitals analyzed, the discounted cash rate offered to self-paying customers for the basic metabolic panel ranged from a low of \$8.46 at several hospitals to a high of \$621.66 at Southern California Hospital (Hollywood, CA).

The lowest negotiated commercial insurance rate for the basic metabolic panel was \$5.82 at several California hospitals. This matched the amount paid by the Medi-Cal fee-for-service rate schedule.

Desert Valley Hospital (Victorville, CA) had the highest negotiated commercial insurance rate (\$559.55 paid by Prime Health Services).

Negotiated Hospital Rates for Basic Metabolic Panel/CPT 80048 in California

	Staffed	Discounted Cash	Minimum Negotiated	Maximum Negotiated	Aetna	Blue Shield	HealthNet
Hospital Name	Beds	Price	Rate	Rate	Commercial	НМО	HMO/PPO
Alta Bates Medical Center (Berkeley, CA)	407	\$102.00	\$8.75	\$161.50	\$127.50	\$125.80	\$125.80
Alvarado Hospital (San Diego, CA)	306	8.46	5.82	256.35	22.87	256.35	10.58
Desert Valley Hospital (Victorville, CA)	148	8.46	5.82	559.55	382.85	458.24	10.58
Garden Grove Hospital (Garden Grove, CA)	167	8.46	5.82	457.06	22.87	8.46	10.58
San Dimas Community Hosp. (San Dimas, CA)	101	8.46	5.82	309.23	22.87	309.23	8.46
Shasta Regional Medical Ctr. (Redding, CA)	226	8.46	5.82	51.67	20.27	6.64	16.92
Sherman Oaks Hospital (Sherman Oaks, CA)	153	8.46	5.82	38.78	22.87	NA	10.58
Southern California Hospital (Hollywood, CA)	612	621.66	15.95	411.13	183.69	17.25	139.86
Sutter Medical Center (Sacramento, CA)	523	136.00	8.00	162.00	128.00	126.00	126.00
West Anaheim Medical Center (Anaheim, CA)	219	8.46	7.27	164.75	22.87	NA	10.58
Unweighted Averages	286	\$91.89	\$7.49	\$257.20	\$95.67	\$163.50	\$46.99

Source: Laboratory Economics from each hospital/price transparency/shoppable service files

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Spotlight Interview with ProPath CEO Cory A. Roberts

ProPath (Dallas, TX), an independent 100%-physician-owned anatomic pathology and clinical laboratory, serves more than 1,000 clients throughout the United States and provides medical directorships at 38 facilities, including 26 hospitals. *Laboratory Economics* recently spoke with ProPath's Chairman, President and CEO Cory A. Roberts, MD.



Cory A. Roberts, MD

How many Covid-19 PCR tests is ProPath doing per day?

We're down nearly 90% from peak. We were doing 2,500 to 3,000 tests per day at our peak, now we're doing less than 500 daily. Right now, we're using Hologic Panther exclusively – we have six in-house.

Our positivity rate on a seven-day rolling average was as high as 28% in late December 2020/early January 2021. Current positivity on a seven-day rolling average is 3.3%. I don't see the Covid test numbers coming back up significantly. Between natural immunity and the aggressive rollout of vaccines, I don't anticipate an additional spike to past levels.

What are you going to do with your excess Covid testing capacity?

Our Panthers will revert to their main function in women's health testing as that division is our largest in the company. We also envision maintaining a lower level of the SARS-CoV-2 testing and potentially adding some more tests to that platform.

How is your routine testing volume?

We forecasted growth for 2021, and we are ahead of forecast right now. The weather took a bite out of our volumes in February, but we are back ahead now. Our top line revenue in 2020 exceeded our 10% projected year over year growth at about 15%. Our Covid testing revenue effectively filled the hole caused by a decline in our core business during the early days of the pandemic.

Are you offering COVID antibody testing?

We are, but we've had very little uptake by clients. My impression is that people don't really know what to do with that information. We have not yet seen a demand for antibody testing in people post-vaccination.

Are there any particular areas of non-Covid testing that are still depressed?

We still have some hospitals that are a little bit behind on procedures although our outpatient work has been pretty robust. We're actually doing more Pap smears than we have in the last several years. The guidelines changed a few years ago and there was a dip, but now we are up about 5% over our previous average. Gastrointestinal biopsies and dermatopathology biopsies are both very strong.

Are you experiencing any shortages in staffing?

It is more difficult to hire because it is such a competitive environment. We have had partnerships with a number of training programs, which has been a great resource for us, and trained people ourselves including starting our own cytotechnology school. We also offer typical incentives for employee referrals. We offer bonuses and relocation expenses if appropriate, and most importantly we make certain we have an excellent culture that draws and retains people. Our retention has improved every year since 2017 and is well ahead of industry. We still have too may open positions, which has put a strain on production, but our team is great and always makes it work for the patients we serve.

Which positions are experiencing the greatest shortages?

There are not many cytotechnologists out there nor pathologists' assistants. Other roles in the laboratory, like laboratory assistants and accessioners, are so key to our process and that can be a fluid staff for us. To combat all of that, in addition to the things I mentioned previously, we have built career paths such that good people can move up but stay within the organization.



Has your total number of employees increased over the past year?

Yes, we are now over 500 employees in 11 states, including over 50 pathologists with more coming. We finished 2019 with about 450 employees and 2020 at 510. We will add more this year but at a slower pace.

Has your laboratory staff been vaccinated against Covid?

We have been able to offer vaccination to our staff going back to January. We have a continuous education campaign going to increase uptake. About 60% of our overall staff has been vaccinated. We offered cash prizes via a random drawing for anyone who submitted proof of full vaccination by the end of March. There seems to be a lack of trust for some folks and a lot of people want to "wait and see." I hope we will get past that. It shocks me that people in the medical field still have a distrust of medicine, but rather than bemoan that fact we need to meet them where they are and ease their fears with facts.

How did ProPath's volume and revenues fare in 2020 compared to 2019?

We passed \$100 million in revenue in 2020, and we also did over one million cases for the first time. For this year, we are anticipating more than 15% top-line growth. That includes Covid testing and everything else. For our core business, excluding Covid, we're looking at about 8% growth. That is organic growth, new sales. We did complete an acquisition in early 2020—New England Tissue Issue (NETI), a dermatopathology lab in Massachusetts. We are continuing to actively pursue acquisitions in addition to our aggressive organic growth which has been at or above 10% annually since 2017.

What do you think the long-term effects of the pandemic will be on ProPath?

I think that we and many others have learned a valuable lesson about supply chains. It also taught us the need to be flexible and nimble—I hope that remains with us as we go forward. It also taught us a lot about cash flow/preservation, and we do daily check-ins from the C-suite, which has improved our ability to communicate with one another. We are intentionally greatly diversified as a company, which will help us respond to the next pandemic or crisis. We have many sources of revenue protecting us from any particular downswing in one business line.

To what extent are you using digital pathology? Do you use it for primary diagnosis?

We have one scanner, an Aperio AT2, that we got at the beginning of 2020. We plan to bring on more scanners this year. We see that as a clear path forward, to level out the work across our team. Glass slides are still primary for our team in our headquarters at this time. We are using digital pathology mostly for partners who are offsite. It's a small portion of our business but growing quickly.

What are your thoughts on the potential to use Artificial Intelligence with digital pathology to improve accuracy and raise pathologist efficiency/case volumes?

I do think there is a role for AI in improving quality and efficiency. We are not currently using specific products for our whole slide imaging but we are evaluating a number of different options as a component of our global digital strategy. Even if efficiency is less than what some tout, I think the addition of AI can improve the product and is a marketable instrument to aid in growth.

Do you plan to expand into any new areas of testing in the next year or so?

Yes, we have a robust FISH testing menu and very good molecular and cytogenetics labs. We're in conversations about what the next needs are in terms of additional testing. We are contemplating what that capital spending might be and whether we might be better suited with a strategic partnership in certain areas. Esoteric testing, both clinically and for sponsored trials, is a growing area for us and a point of concentration.



Huge Government Contracts For Covid Testing At Schools (cont'd from page 1)

HHS, in collaboration with the Army Contracting Command, requested that interested parties submit a five-page white paper with initial proposals by March 15. Based on these white papers, HHS then invited certain organizations to submit formal bids by April 1. The final awards will be made on April 27.

The government will not release any information pertaining to the number or names of organizations invited to submit bids. However, Laboratory Economics believes LabCorp, Quest Diagnostics and Thermo Fisher Scientific were among those invited to make formal bids. There is the poten-

School Testing Coordination Regions							
Region	States	Total Population					
West	AK, AZ, CA, HI, ID, NV, OR, WA	66 million					
Midwest	CO, IA, IL, IN, KS, MI, MN, MO, MT, ND, NE, OH, SD, UT, WI, WY	79 million					
Northeast	CT, DE, MA, MD, ME, NH, NJ, NY, PA, RI, VA, VT, WV	78 million					
South	AL, AR, FL, GA, KY, LA, MS, NC, NM, OK, SC, TN, TX	110 million					
	t. of Health & Human Services am.gov/opp/a249f888e350420b89f64ed nents-links)	669b8ad613/					

tial for one organization to win multiple regions.

Each winning regional coordinator will need to conduct outreach to local school districts and homeless shelters to develop and implement testing programs. They will also need to contract with labs to perform testing. However, if LabCorp, Quest Diagnostics or another large laboratory wins a contract, they could potentially

perform most of the testing in-house. Any subcontracted labs will be paid by the winning regional coordinator. No third parties, such as health insurers, will be billed under the program.

Actual testing of school children under the program is expected to begin within six weeks after award of the regional coordinator contracts. This would place the start of actual testing at around mid-June—just as the school year is ending.

The Association of Public Health Laboratories (APHL-Silver Springs, MD) has stated concerns that the dire need for this expanded testing may be past. HHS says that maintaining high levels of testing, as vaccination rolls out and transmission decreases, is critical to controlling this pandemic, and to preventing another wave.

U.S. Covid-19 PCR testing volume peaked in early January at approximately 2.1 million tests per day (avg. positivity rate of 13.9%). Daily test volumes currently average approximately 1.3 million (avg. positivity rate of 5%).

Lighthouse Lab Services Acquires Vachette Pathology

Tachette Pathology (Sylvania, OH) was acquired by Lighthouse Lab Services (Charlotte, NC) in early April. Vachette provides auditing services to pathology groups and labs and was founded by its President, Mick Raich, in 2002. Lighthouse is a lab consulting firm focused on licensure and compliance with CLIA, COLA and CAP accreditation requirements, as well as test development and validation for a variety of applications ranging from toxicology to infectious disease.

Vachette, which has 16 full-time employees, will maintain its office in Sylvania (a suburb of Toledo).

"Vachette is growing at a fast pace. Being able to access Lighthouse's IT, HR, and business operational experience will help us manage this growth and provide better value to both our clients and our employees," according to Raich, who is now President, RCM Consulting, at the combined company.



How Much Longer Until Digital Pathology Takes Off?

Keith Kaplan, MD, is a pathologist at Alliance Pathology Consultants (Hoffman Estates, IL), which serves the AMITA Health system in greater Chicago. His subspecialty interests include gastrointestinal and hepatic pathology, cytopathology, and pathology informatics. Dr. Kaplan is also Chief Medical Officer at Corista (Concord, MA), which markets integrated digital pathology systems, and is founder and author of the tissuepathology.com blog, which focuses on digital pathology and informatics. Below we summarize Dr. Kaplan's views on several key issues related to digital pathology.



Keith Kaplan, MD

Has the pandemic accelerated the adoption of digital pathology in the United States? Contrary to what you might think, it really hasn't.

Early last spring the FDA granted a waiver for the use of readily available consumer monitors for digital pathology interpretations for the duration of the public health emergency. The intent was to facilitate remote pathology services to help reduce personnel contact and risk of exposure to the coronavirus.

However, the temporary restrictions on elective procedures and slowdown in physician office visits resulted in pathology case volume declines of as much as 80-90% last spring. So, although well-intentioned, the regulatory flexibility was more than offset by a severe reduction in demand for pathology services—at least during the early months of the pandemic.

Furthermore, the idea that pathologists would be working safely at their home offices, while other doctors and nurses put their health at risk by going to the hospital just wasn't going to fly. Pathologists at our group were expected to show up at work every day just like everyone else.

So where do we stand in the long-anticipated transition to digital pathology?

There has been slow progress since the first commercial whole slide scanners began entering the market some 20 years ago. The FDA clearance of several digital pathology systems [Philips in 2017 and Leica in 2019] for primary diagnosis and related supporting research have given confidence that the quality of reading digital images is as good as, if not better than, conventional light microscopy. Arguments over image quality issues have been put to rest.

However, economic barriers still exist. Unlike digital radiology where the elimination of film made return on investment (ROI) clear, the ROI on digital pathology equipment is less obvious. A good quality scanner, medical-grade monitor and software can require an upfront investment of roughly \$200,000 plus ongoing licensing and support fees. All in, it probably costs the typical histology lab an average of roughly \$1 per digitized slide—without eliminating the need to first create a traditional glass slide.

The assumption had always been that a new CPT code would be created with technical reimbursement that covered the cost of scanning and archiving digital images. But this hasn't occurred, and it's made the value proposition of converting to digital pathology more difficult to prove.

In addition, changing the workflow and habits of pathologists is a challenge. An experienced pathologist working with a stack of glass slides and a microscope may be more efficient than a pathologist searching for and downloading digitized images at a computer.



What's your best guesstimate for the percentage of glass slides that are currently being interpreted by digital pathology in the clinical setting?

Assuming an estimated 100 million to 120 million histology slides are prepared each year in the United States, then I would say less than 5% are currently being digitized for initial primary diagnosis. I can't imagine the U.S. number presently exceeds 5 million.

Have pathologist residency programs begun training new pathologists using digital pathology?

None that I'm aware of—the demand in the market just isn't there yet.

What about the new artificial intelligence algorithms that have been developed to assist pathologists reading digitized slides?

There are currently about half-a-dozen pathology AI companies that have developed clinical-decision-support algorithms to assist pathologists in reviewing cases. The initial research and data does indicate that these programs can help improve the level of accuracy and efficiency of pathologists.

I think it has been proven time and time again that image analysis (and presumably artificial intelligence) algorithms are more reproducible and accurate when quantifying slide-based material. For example, immunohistochemical stains for ER or HER2 or Ki-67 can be judged with much greater reproducibility and consistency with computer-assisted diagnosis than with manual semi-quantitative methods at a light microscope. In the future, detection of rare events (i.e., isolated tumor cells) or percent and grade of tumor involving a core biopsy will likely be more reproducible and consistent with machine technologies than with pathologist alone.

At the same time, as a practicing pathologist, I'm always a little bit leery of anyone who says they can make me more efficient. Increasing your case volume by 10-20% or more per day with AI may not be such a good deal for pathologists. And we're not in a dire situation yet in terms of pathologist retirements.

Couldn't the big national labs combine digital pathology with AI to create mega-AP labs that reduce their reliance on interpretations by employed pathologists?

Certainly. It's all about scale. Larger laboratories with more pre-screening, automation, standardized diagnoses, in-house support for transcription and pulling slides and the like will have a competitive advantage as digital pathology becomes pathology.

Why have pharmaceutical/drug discovery/contract research organizations been quicker to adopt digital pathology?

I think the "bar" was lower in terms of showing Good Laboratory Practices (GLP) in pre-clinical to analyze huge data sets with many similarities and minor differences across those studies for drug effect, efficacy and/or toxicology. For pre-clinical, the emphasis was on further analyzing the tissue with computers and workflow management which provided an advantage to adoption compared with the heterogeneous data sets and staining often encountered in clinical practice. The drug development market has been a life-saver for digital pathology vendors.

So how does the adoption of digital pathology for clinical diagnosis play out from here?

There will come a day when new pathologists have never seen or used a traditional light microscope, but the transition will continue to occur gradually. There'll be no tidal wave any time soon. The transition is occurring via niche adoption in areas like remote digital slide analysis of frozen sections, second opinions and consults, and tumor boards and conferences.



Spotlight Interview With Mako Medical Labs' Steve Hoover

As Medical Laboratories (Raleigh, NC) was initially formed in 2014 by CEO Chad Price and COO Josh Arant. The inital focus was on toxicology testing. The company expanded into full-service reference testing by opening a second laboratory in Henderson, North Carolina in early 2018. Over the past 12 months, Mako Medical has performed more than six million Covid-19 PCR tests. *Laboratory Economics* recently spoke with Steve Hoover, Vice President of Operations.



Steve Hoover

Can you describe Mako's involvement in Covid-19 testing?

Prior to the start of the pandemic, Mako was fortunate to be operating two of ThermoFisher's QuantStudio 12K Flex analyzers at our Henderson lab. We redirected those analyzers and started Covid-19 PCR testing on April 1, 2020.

Initial Covid-19 PCR test volumes averaged a few hundred tests per day. Over the course of the past 12 months, we added 20 more QuantStudio 12K Flex analyzers as well as Hologic Panther, Cepheid GeneXpert Infinity and Qiagen QiaSTAT analyzers.

Our peak Covid-19 PCR test volumes hit as high as 55,000 to 60,000 per day in November and December. We are currently performing Covid testing in 43 states with total volumes averaging between 15,000 and 20,000 tests per day and potential capacity of up to 150,000 per day.

What's your average turnaround time for Covid-19 PCR testing?

Ninety-four percent of our samples have been resulted in less than 24 hours, and 99% in under 48 hours.

Are you experiencing any supply shortages?

Not currently. We've got more than two million Covid-19 PCR test kits on hand. However, the huge shift toward manufacturing Covid test reagents has led to supply shortages for certain other PCR tests, including chlamydia/GC.

How about on the staffing front?

Pre-pandemic, we had about 350 employees, which has grown to approximately 1,100. For example, our patient accessioning staff has grown from 20 employees to 400, while our technical staff for PCR testing has grown from four employees to 250. The most difficult staff to find have been medical technologists and lab technicians.

How has the transition to the new Medicare billing code (U0005) for two-day turnaround gone? It's not easy and requires some manual processes. Certain private insurers have followed Medicare's new coding, others have not.

Have your non-Covid test volumes recovered?

Our non-Covid test volumes fell by as much as 40% during the first few weeks of the pandemic. They have since rebounded and are now roughly double pre-pandemic levels. We've added hundreds of new clients for Covid testing and many have chosen to use us as their full-service lab.

Have your employees been vaccinated?

We started on-site vaccinations at our Henderson lab in late January through a partnership with a local pharmacy. Although Mako doesn't mandate employee vaccinations, the majority have chosen to get the shots.

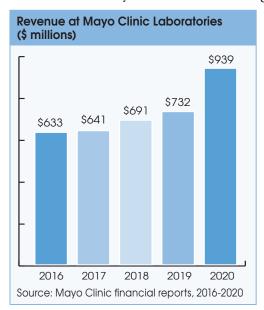
As the pandemic recedes, what will you do with all the PCR test capacity you have built up? We expect some level of Covid testing to continue for a long time, including screening programs at schools and universities. We'll use spare PCR testing capacity to expand our menu of non-Covid molecular diagnostic tests and for clinical research testing opportunities.



Mayo Clinic Labs Reports Record Revenue Boosted By Covid Testing

ayo Clinic Laboratories (Rochester, MN), the global reference laboratory owned by Mayo Clinic, performed 3.1 million Covid-19 tests last year, which helped the lab's revenue grow by more than 28% to a record \$939 million in 2020, according to Mayo Clinic's financial report for the 12 months ended December 31, 2020.

"It does reflect the fact that Mayo Clinic Laboratories played a significant part in the testing environment, really for the nation, during 2020," said Dennis Dahlen, Chief Financial Officer



for Mayo Clinic. "The rest of our lab volumes were impaired for the year in total." Overall last year, the lab served 4.5 million unique patients, performed roughly 25 million tests, and received specimens from over 4,000 domestic hospitals.

Overall, Mayo Clinic reported revenue of \$13.9 billion in 2020, a 1.5% increase from \$13.7 billion in 2019. Net operating income was \$728 million, which was down from \$952 million in 2019.

Mayo Clinic, which operates flagship hospitals in Minnesota (2,059 beds), Arizona (304 beds) and Florida (304 beds), reported that hospital admissions were down 11% to 116,942 in 2020, while outpatient visits declined by 13% to 4.278 million.

Medicare add-on payments for hospitals treating Covid

patients, CARES Act funding and increased lab revenue from Covid testing were among the factors that helped offset the decline in patient volume at Mayo last year.

In 2020, Mayo Clinic cared for 65,283 outpatients that tested positive for Covid-19 and 4,918 Covid-19 inpatients with more than 1,000 patients requiring ICU care.

Mayo Clinic's 2020 financial results included \$182 million in federal funding it received through the CARES Act. Mayo Clinic had received a total of \$338 million last year from the CARES Act, but returned a total of \$156 million. The clinic decided to keep a sum roughly equal to the federal funds used in March, April and early May, Dahlen said, and opted to return the rest after its financial picture stabilized.

NeoGenomics' Long-Time CEO Doug VanOort Retires

NeoGenomics' Chairman and CEO Douglas M. VanOort, age 65, retired as CEO on April 19, 2021. VanOort will remain as Executive Chairman of the Board. Mark Mallon, age 58, who recently served as CEO of Ironwood Pharmaceuticals and is a former Executive Vice President of Astra Zeneca, has become NeoGenomics' CEO and a board member.

VanOort had been Chairman and CEO of NeoGenomics since late 2009. During that time, the company has become one of the largest lab companies in the nation, with revenues increasing from \$20 million to the current run-rate of approximately \$500 million. NeoGenomics' share price increased at an average annual rate of 34% between October 28, 2009 to April 19, 2021.

VanOort owns 3.2 million shares of NeoGenomics with a current market value of approximately \$160 million.



Publicly-Traded Lab Revenue Jumped 23% In 2020

On a combined basis, 22 publicly-traded labs reported a revenue increase of 23.4% to \$25.1 billion in full-year 2020 (after adjusting for acquisitions), according to financial reports collected by *Laboratory Economics*.

Among five national clinical labs (Quest Diagnostics, LabCorp, Sonic, BioReference and Enzo), combined revenue increased by 26.8% (after adjusting for acquisitions). BioReference had the strongest revenue growth, up 76.2% to \$1.262 billion, driven by Covid-19 testing. BioReference performed 10.1 million PCR tests and 800,000 antibody tests for Covid-19 in 2020.

Among 17 specialty and genetic testing labs, combined pro-forma revenue increased by 7.7%. Proforma revenue growth was fastest at Biocept (San Diego, CA), up 397% to \$27.5 million. Biocept's growth was driven by 188,000 Covid-19 PCR tests that produced \$23.3 million of revenue in 2020.

Revenue Growth at 22 Publicly-Traded Lab Companies (\$000)

	Full-Year	Full-Year	Reported	Pro Forma
Company	2020	2019	Change	Change*
LabCorp (lab testing only)	\$9,253,400	\$7,000,100	32.2%	30.9%
Quest Diagnostics (lab testing only)	9,139,000	7,405,000	23.4%	21.6%
Opko/Bio-Reference Labs	1,262,242	716,434	76.2%	76.2%
Sonic Healthcare USA ¹	1,222,200	1,008,416	21.2%	3.0%
Enzo Clinical Labs (lab testing only) ²	47,964	51,115	-6.2%	-6.2%
Total, 5 National/Clinical Labs	\$20,924,806	\$16,181,065	29.3%	26.8%
Exact Sciences	\$1,491,391	\$876,293	70.2%	17.7%
Myriad Genetics ³	638,600	851,100	-25.0%	-25.0%
NeoGenomics	444,448	408,830	8.7%	6.2%
Natera	391,005	302,328	29.3%	29.3%
Guardant Health	286,730	214,375	33.8%	33.8%
Invitae Corp.	279,598	216,824	29.0%	29.0%
CareDx	192,194	127,068	51.3%	51.3%
Veracyte	117,483	120,368	-2.4%	-2.4%
Progenity	74,313	143,985	-48.4%	-48.4%
Castle Biosciences	62,649	51,865	20.8%	20.8%
Biodesix	45,557	24,552	85.6%	85.6%
Exagen Inc.	41,975	40,387	3.9%	3.9%
Interpace Biosciences	32,398	24,220	33.8%	33.8%
Biocept	27,461	5,529	396.7%	396.7%
Psychemedics	21,360	37,678	-43.3%	43.3%
Dermtech	5,885	3,364	74.9%	74.9%
Aspira Women's Health	4,651	4,538	2.5%	2.5%
Total, 17 Specialty/Genetic Labs	4,157,698	3,453,304	20.4%	7.7%
Grand Total, All 22 Lab Companies	\$25,082,504	\$19,634,369	27.7%	23.4%

^{*}Pro forma change is estimated by Laboratory Economics after adjustments for acquisitions.

Source: Laboratory Economics from company reports

¹Sonic Healthcare USA revenue is for the 12 months ended June 30, 2020 at constant exchange rate of 1 Australian Dollar equal to 0.70 U.S. Dollar. ²Enzo's revenue is for lab services only for 12 months ended July 31, 2020. ³Myriad Genetics revenue is for the 12 months ended June 30, 2020.

Lab Stocks Up 13% Year To Date

Twenty-two lab stocks have risen by an unweighted average of 13% year to date through April 16. In comparison, the S&P 500 Index is up 11% thus far in 2021. The top-performing lab stocks so far have been Interpace Biosciences, up 147%; Myriad Genetics, up 38%; and Derm-Tech, up 34%. Shares of LabCorp are up 29% year to date, and Quest Diagnostics is up 9%.

	Stock Price	Stock Price	2021 Price	Enterprise Value	Enterprise Value/	Enterprise Value/
Company (ticker)	4/16/21	12/31/20	Change	(\$ mill)	Revenue	EBITDA
LabCorp (LH)	\$262.20	\$203.55	29%	\$31,040	2.2	10.2
Exact Sciences (EXAS)	130.04	132.49	-2%	21,390	14.3	NA
Quest Diagnostics (DGX)	130.11	119.17	9%	20,720	2.2	8.6
Sonic Healthcare (SHL.AX)*	35.71	32.15	11%	19,930	2.5	9.8
Guardant Health (GH)	158.50	128.88	23%	14,980	52.2	NA
Natera (NTRA)	106.95	99.52	7%	8,840	22.6	NA
Invitae (NVTA)	37.64	41.81	-10%	7,780	27.8	NA
NeoGenomics (NEO)	49.34	53.84	-8%	5,750	12.5	200.5
CareDx (CDNA)	74.27	72.45	3%	3,640	19.0	NA
Opko Health (OPK)	4.34	3.95	10%	2,940	2.1	18.9
Veracyte (VCYT)	48.17	48.94	-2%	2,890	21.8	NA
Myriad Genetics (MYGN)	27.31	19.77	38%	2,270	4.1	NA
Castle Biosciences (CSTL)	65.51	67.15	-2%	1,300	20.8	NA
DermTech Inc. (DMTK)	43.46	32.44	34%	1,200	204.8	NA
Aspira Women's HIth (AWH)	6.10	6.71	-9%	670	144.1	NA
Biodesix (BDSX)	19.37	20.16	-37%	469	10.3	NA
Progenity (PROG)	3.37	5.31	-37%	296	4.0	NA
Exagen (XGN)	16.62	13.20	26%	246	5.9	NA
Enzo Biochem (ENZ)	3.33	2.52	32%	153	1.6	NA
Biocept (BIOC)	4.36	4.44	-2%	60	6.2	NA
Psychemedics (PMD)	6.80	5.09	34%	45	2.1	NA
Interpace Biosciences (IDXG)	7.75	3.14	147%	31	1.0	NA
Unweighted Averages			13%	\$146,639	26.5	49.6

*Sonic Healthcare's figures are in Australian dollars

Source: Laboratory Economics from company reports and Capital IQ

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U.S. Covid-19 Statistics & Analysis

Based on data from CDC, an estimated 43% of the U.S. population had been infected with Covid-19 as of April 17, while 24% has been fully vaccinated. The peak in daily new U.S. confirmed cases came on Jan. 7, 2020.

Separately, the personal finance website WalletHub has an ongoing study that compares the 50 states and the District of Columbia across 14 key metrics (e.g., face mask requirements, travel restrictions, large gathering restrictions, school closings, restaurant and bar closings, etc.) in order to determine the states with the fewest coronavirus restrictions and those with the most restrictions. (See https://wallethub.com/edu/states-coronavirus-restrictions/73818)

The 10 states (CA, DC, VA, VT, MA, HI, ME, WA, CT, NY) that have had the most restrictions over the course of the pandemic have a weighted-average population infection rate of 44% and an average of 1,749 Covid-19 deaths per million.

The 10 states (IA, SD, OK, FL, ID, AK, UT, SC, MO, AR) that have had the fewest restrictions have a weighted-average population infection rate of 39% and an average of 1,571 Covid-19 deaths per million.

U.S. Covid-19 Statistics (as of April 17, 2021)

State	Population	Confirmed Cases	% Population Naturally Infected*	% Population Fully Vaccinated	Covid Deaths	Deaths/ 1 Million
New Jersey	8,882,190	975,704	71%	29%	25,134	2,830
New York	19,453,561	2,039,325	67%	28%	51,818	2,664
Massachusetts	6,892,503	671,250	63%	29%	17,455	2,532
Rhode Island	1,059,361	144,149	62%	31%	2,647	2,499
Mississippi	2,976,149	309,029	60%	21%	7,153	2,403
Arizona	7,278,717	853,050	59%	24%	17,151	2,356
Connecticut	3,565,287	329,062	56%	31%	7,995	2,242
Louisiana	4,648,794	451,955	55%	23%	10,282	2,212
South Dakota	884,659	121,056	55%	31%	1,953	2,208
Alabama	4,903,185	522,131	55%	19%	10,790	2,201
Pennsylvania	12,801,989	1,108,538	50%	26%	25,773	2,013
Indiana	6,732,219	707,111	49%	22%	13,216	1,963
North Dakota	762,062	105,696	49%	29%	1,479	1,941
New Mexico	2,096,829	194,868	48%	32%	4,001	1,908
Illinois	12,671,821	1,299,575	47%	24%	23,945	1,890
Arkansas	3,017,804	333,407	47%	21%	5,693	1,886
lowa	3,155,070	388,890	47%	28%	5,881	1,864
Georgia	10,617,423	1,083,300	47%	19%	19,757	1,861
South Carolina	5,148,714	568,258	45%	23%	9,321	1,810
Michigan	9,986,857	873,700	45%	25%	17,934	1,796
Tennessee	6,829,174	830,484	44%	20%	12,049	1,764
Nevada	3,080,156	310,235	44%	23%	5,365	1,742
Texas	28,995,881	2,852,779	43%	22%	49,785	1,717
Kansas	2,913,314	307,729	43%	26%	4,987	1,712

		Con- firmed	% Population Naturally	% Population Fully	Covid	Deaths/
State	Population	Cases	Infected*	Vaccinated	Deaths	1 Million
Oklahoma	3,956,971	444,863	42%	26%	6,697	1,692
Delaware	973,764	100,777	41%	25%	1,602	1,645
Ohio	11,689,100	1,052,099	41%	26%	18,991	1,625
Florida	21,477,737	2,162,067	40%	24%	34,412	1,602
District of Columbia	705,749	46,579	39%	23%	1,095	1,552
West Virginia	1,792,147	148,517	39%	26%	2,780	1,551
California	39,512,223	3,717,019	39%	24%	60,988	1,544
Missouri	6,137,428	576,569	38%	23%	9,326	1,520
Montana	1,068,778	107,089	36%	27%	1,545	1,446
Kentucky	4,467,673	437,037	35%	27%	6,330	1,417
Maryland	6,045,680	434,859	35%	27%	8,545	1,413
Minnesota	5,639,632	554,536	31%	28%	7,073	1,254
Virginia	8,535,519	644,828	31%	26%	10,564	1,238
Wyoming	578,759	57,267	30%	24%	691	1,194
North Carolina	10,488,084	943,693	30%	24%	12,387	1,181
Wisconsin	5,822,434	589,940	29%	28%	6,711	1,153
Nebraska	1,934,408	216,297	29%	27%	2,213	1,144
Idaho	1,787,065	184,769	28%	23%	2,017	1,129
Colorado	5,758,736	489,028	27%	25%	6,330	1,099
New Hampshire	1,359,711	91,279	23%	28%	1,266	931
Washington	7,614,893	387,631	18%	26%	5,430	713
Utah	3,205,958	392,509	17%	19%	2,164	675
Oregon	4,217,737	174,501	15%	25%	2,460	583
Maine	1,344,212	56,939	14%	32%	764	568
Alaska	731,545	63,245	11%	32%	329	450
Vermont	623,989	21,869	10%	30%	242	388
Hawaii	1,415,872	31,270	8%	28%	474	335
10 most restrictive	89,663,808	7,945,772	44%	28%	156,825	1,749
states (CA, DC, VA, VT,						
MA, HI, ME, WA, CT,						
NY)						
10 least restrictive	49,502,951	5,235,633	39%	25%	77,793	1,571
states (IA, SD, OK, FL,						
ID, AK, UT, SC, MO, AR)						
10 oldest states	53,880,387	5,138,901	48%	28%	102,615	1,904
(ME, VT, NH, WV, FL,						
CT, PA, DE, RI, NJ)						
10 youngest states	89,636,857	8,782,946	39%	24%	138,461	1,545
(UT, AK, TX, ND, ID,						
CA, NE, OK, DC, CO)						
U.S. Totals	328,239,523	31,508,357	43%	24%	564,990	1,721

^{*}Estimated based on infection fatality rate of 0.4% (i.e., Covid deaths/0.4%=estimated infections) Source: Laboratory Economics from CDC, Worldometers.com and WalletHub.com