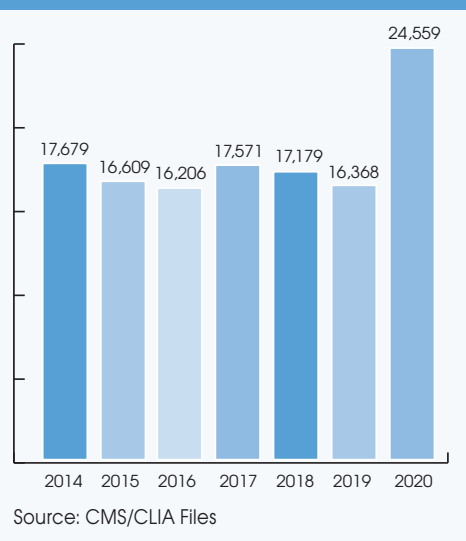




Covid Testing Spurs New Lab Boom

The extraordinary demand for Covid-19 testing resulted in a record number of new CLIA lab certifications last year, according to CMS data analyzed by *Laboratory Economics*. A total of 24,559 new labs were issued CLIA certificates in 2020, up 50% from 16,368 in 2019. The greatest number of new lab creations occurred at physician offices (7,137 new labs), pharmacies (3,539) and assisted living facilities (2,953). The big question now is what happens to these new labs and the enormous amount of PCR testing capacity that has been built up as the pandemic and related testing demand recede? Daily Covid-19 PCR testing volume has fallen by about 50% since peaking in early January. *Full details on page 11.*

New CLIA Lab Certifications



United Moving Ahead With New DDP Benefit Design

UnitedHealthcare says it's moving ahead with its requirement for all in-network labs to qualify as "Designated Diagnostic Providers" in order to get paid for clinical lab tests and anatomic pathology services provided to non-inpatients for its fully-insured commercial health plans. Despite protests from the American Hospital Association and College of American Pathologists, a UHC spokesperson says the effective date for the new benefit design remains July 1, 2021. (See *LE*, February 2021).

Quest Diagnostics To Buy Mercy's Outreach Lab

Quest Diagnostics has agreed to acquire the clinical laboratory outreach business of Mercy (St. Louis, MO) in an all-cash asset transaction. The deal is expected to close in the second quarter of 2021. The purchase price has not yet been disclosed. *Full details on page 2.*

CONTENTS

HEADLINE NEWS

- Covid Testing Spurs Lab Boom..... 1, 11
- UHC Pushing Ahead With New Lab Network Tier 1
- Quest Diagnostics To Buy Mercy's Outreach Lab Business..... 1-2

SPOTLIGHT INTERVIEWS

- Stanford University's Jay Bhattacharya, MD, PhD 3-4
- Conway Regional Lab's Marianne Black 5
- GENETWORx Lab's William Miller 8

ACLA MEETING HIGHLIGHTS

- PAMA Update..... 6
- Stark Law and AKS Changes 6
- The Pandemic and Technology Adoption 7
- ACLA Elects New Board Members..... 7

DIGITAL PATHOLOGY & AI

- Labcorp To Use PathAI For Drug Trials 7
- Ibex Raises \$38 Million 7

MEDICARE & MEDICAID

- California Finalizes Some Medi-Cal Rate Cuts..... 9

FINANCIAL

- Toxicology Labs Average \$458 Per Medicare Patient..... 10
- Enzo Making CEO Change..... 11
- Lab Stocks Up 16% YTD..... 12

STATISTICAL ADDENDUM

- Estimated Covid-19 Cases for all 50 U.S. States..... 13-14

Quest Diagnostics To Buy Mercy's Outreach Lab (cont'd from page 1)

Mercy's clinical laboratory outreach business currently operates from 29 hospital laboratories and two independent clinic labs serving physicians in Arkansas, Kansas, Missouri and Oklahoma. Mercy's primary outreach clients include Mercy Clinic, which has 900 physician practices and outpatient facilities that employ more than 4,000 physicians and advanced practitioners.

Under the acquisition agreement, Mercy's clinical lab outreach testing will be transitioned to Quest's regional lab in Lenexa, Kansas as well as several smaller Quest labs in the Midwest.

Mercy will continue to own and operate its hospital-based labs and perform inpatient and hospital-based outpatient testing. In addition, the deal with Quest does not involve anatomic pathology services, nor does it include a contract for Quest to provide reference testing services to Mercy.

A Quest spokesperson says that employees who work in Mercy's outreach lab will be offered the opportunity to transition to Quest as part of the transaction. Quest also expects to add positions to its Lenexa laboratory as volume increases.

"This relationship gives our patients and providers more convenient locations for sample collection and a significantly lower cost of testing while maintaining the same high quality patients and providers need," according to Lynn Britton, President and CEO at Mercy.

Mercy's largest clinical laboratory outreach testing sites are located at Mercy Hospital Oklahoma City, Mercy Hospital St. Louis and Mercy Hospital Fort Smith. Overall, Mercy's clinical lab outreach business generated more than \$14 million in Medicare CLFS payments in the fiscal year ended June 30, 2020. *Laboratory Economics* estimates that Mercy's overall clinical lab outreach business has annual revenue of more than \$70 million.

Other large hospital lab outreach businesses that Quest has acquired over the past several years include Memorial Hermann Diagnostic Laboratories (Houston, TX) for \$120 million in cash in April 2020 and PeaceHealth Laboratories (Vancouver, WA) for \$101 million in cash in May 2017.

Mercy Laboratory Services Overview

Hospital Name	Location	Staffed Beds	Annual Lab Dept. Cost	Medicare CLFS Payments	Total Est'd Clinical Lab Outreach Revenue
Mercy Hospital Oklahoma City	Oklahoma City, OK	308	\$38,422,929	\$3,693,880	\$18,469,400
Mercy Hospital St. Louis	St. Louis, MO	859	62,526,398	3,064,416	15,322,080
Mercy Hospital Fort Smith	Fort Smith, AR	385	15,182,232	2,420,712	12,103,560
Mercy Hospital Springfield	Springfield, MO	672	37,245,247	989,891	4,949,455
Mercy Hospital South	St. Louis, MO	767	28,506,361	794,262	3,971,310
Mercy Hospital Jefferson	Festus, MO	321	10,534,009	658,008	3,290,040
Mercy Hospital Northwest Arkansas	Rogers, AR	275	18,472,067	623,750	3,118,750
Mercy Hospital Joplin	Joplin, MO	241	18,518,189	842,004	4,210,020
Mercy Hospital Ardmore	Ardmore, OK	180	9,608,551	531,975	2,659,875
Mercy Hospital Ada	Ada, OK	148	7,242,254	448,524	2,242,620
Total 10 Mercy Hospitals		4,156	\$246,258,237	\$14,067,422	\$70,337,110

Source: Hospital Cost Reports for fiscal year ended June 30, 2020 and Laboratory Economics estimates

Spotlight Interview With Stanford's Jay Bhattacharya

Jay Bhattacharya, MD, PhD, is a physician, epidemiologist and health policy economist at Stanford University. His research focuses on the economics of health care around the world with an emphasis on vulnerable populations. Here is a summary of our discussion in early March.



You recently co-authored a peer-reviewed study comparing Covid-19 policy responses in different countries. What did you find?

The study investigated measures by England, France, Germany, Iran, Italy, Netherlands, Spain, the U.S., South Korea and Sweden. The first eight countries imposed various stay-at-home orders on their citizens and business closures, while South Korea and Sweden took less restrictive steps. We found no clear, significant beneficial effect of more restrictive measures on coronavirus case growth in any country. [See *Assessing Mandatory Stay-At-Home and Business Closure Effects on the Spread of Covid-19*, *European Journal of Clinical Investigation*, Jan. 5, 2021.]

The experience within the United States has been similar. For example, California has had the most restrictive policies, while Florida has been among the least restrictive. However, their Covid-19 deaths per capita are nearly identical [see pages 13-14]. In fact, after adjusting for Florida's older population (median age of 42) as compared with California's younger population (median age of 36.5), Florida has actually had fewer Covid-19 deaths per capita.

There is no evidence that business and school closures contributed in any meaningful way to bending the curve of new cases in the United States or anywhere else.

Nationwide lockdowns had never been used in any previous pandemic, so why this time?

At the beginning of the current pandemic, public health officials were assuming that coronavirus was far more deadly than it turned out to be. The World Health Organization and Dr. Anthony Fauci initially estimated that the infection fatality rate (IFR) for Covid-19 was 3.4% and more than ten times deadlier than the seasonal flu. But they greatly underestimated the number of asymptomatic cases, which inflated their initial IFR estimates. The policy implications of this mistake have been enormous.

We now know that the IFR is between 0.2% and 0.4% for the overall population with a strong age gradient in risk of death. The infection survival rate is 99.95% for people under 70 and 95% for people over 70. Another way to look at it is, for every eight years of age, your risk of dying from Covid-19 doubles. For example, a 60-year-old individual has double the risk of a 52 year old, but half the risk of a 68 year old.

Other factors, such as heart disease, diabetes and obesity, raise your risk of dying from Covid, but age plays the biggest role by far.

The CDC now estimates that the actual number of Covid-19 cases is 4.6 times the number of confirmed cases. Your thoughts?

The CDC is still underestimating the number of cases because their estimates are based on antibody studies. They do not consider the fact that antibodies begin fading after six months. If you adjust for the fading of antibodies, the actual number of people that have had coronavirus is between six and eight times higher than the number of confirmed cases in the United States. That translates into more than 50% of Americans having already had the disease.

How did previous pandemics end?

The influenza pandemics of 1918-1919, 1957-1958 and 1968-1969 each ended with herd immunity by natural infection. The more recent 2009 H1N1 Pandemic was stopped by herd immunity achieved through a combination of natural infection and vaccination.

What exactly is herd immunity?

Herd immunity is the point in a pandemic at which every newly infected person transmits the disease to less than one additional person. After this threshold has been reached, cases begin to drop leading to the end of a pandemic. An epidemiologist who does not believe in herd immunity is like a physicist who does not believe in gravity.

With Covid-19, can herd immunity be avoided?

Absolutely not. Sooner or later, herd immunity will be reached either through natural infection or through a combination of vaccinations and natural infection.

What about the new variants from the United Kingdom, South Africa and Brazil?

Immunity gained through natural infection or vaccination still both appear to prevent hospitalizations and death even when new variants are the cause of infection. These new variants are what you would expect to see near the end of a pandemic. The new and more contagious variants represent a last gasp effort on the part of the virus to stay in circulation as the pandemic nears its end.

Should public health agencies like CDC and NIH play any role in a pandemic?

I don't question the role of all public health interventions or coordinated communications about the pandemic. But stay-at-home orders and business and school closures have provided little benefit, if any at all, compared with the tremendous harm they have caused.

Among the harmful effects of restrictive lockdowns have been increased opioid-related overdoses, missed vaccinations, less cancers being detected at an early, treatable stage, domestic abuse and suicides.

In particular, I believe the closure of in-person schooling may turn out to be the single biggest generator of inequality since segregation.

In addition, the lockdown's effect on worldwide poverty, malnutrition and hunger will be staggering. For example, the United Nations has estimated that the collateral economic damage from lockdowns has pushed an additional 130 million people in the world to the brink of starvation.

So what is the most effective policy for dealing with Covid-19 that causes the least amount of harm?

Since Covid-19 operates in a highly age-specific manner, mandated counter measures as well as vaccination strategy should also be targeted at the most vulnerable groups.

For example, nursing home staff, who often cover multiple facilities, should be limited to working at a single location to lower the chance of cross exposure. Rapid antigen testing should be widely used to test patients, staff and visitors, and infected patients should be segregated until they get better.

Similarly, the roll-out of vaccinations should be targeted at the elderly who have not previously been infected and recovered from Covid-19. This would optimize limited initial supplies, help us reach herd immunity faster and save more lives. We know that natural immunity is highly protective and lasts for a minimum of eight months and probably much longer—most likely at least two to three years.

How do you see this pandemic, associated restrictions and fear ending?

Protection by natural immunity and vaccination should continue to lower the number of hospitalizations and deaths. Eventually the disease will be defanged and the spell of fear will break. Even so, Covid-19 is not going to be fully eradicated. I expect it to become seasonally endemic. We have to learn to live with this disease. More importantly, we have to research and quantify the harm caused by ineffective health policy decisions, so they are never adopted again for future pandemics.

Spotlight Interview with Conway Regional Lab's Director Marianne Black

Conway Regional Laboratory, which serves patients throughout Arkansas, typically performs about 2 million lab tests per year, including roughly 50% from outreach testing. When Covid-19 hit early last year, the lab scrambled to acquire platforms for Covid testing. *Laboratory Economics* recently spoke with Lab Director Marianne Black.



Tell us about Conway Regional Laboratory.

Conway Regional Medical Center (150 beds) is about 40 miles north of Little Rock. About 20 years ago, the hospital launched a lab outreach program geared toward commercial clients, including drug screening for local employers and testing for employee health programs. As time has gone by, the lab outreach program has expanded to meet the needs of other clients, such as clinics and nursing homes. Five years ago, Conway Regional began to expand its footprint, including through acquisition of physician practices and employment of physicians. Two years ago, Conway entered into an agreement with Dardanelle Regional Medical Center to manage that hospital as well.

Our lab and hospital serve the five counties that surround Conway to the north and west, which are primarily rural counties. Lab outreach has expanded—we now have about 50 outreach clients. At one point, we were growing 12% to 18% per year, but that has leveled off. The lab has a total of about 90 employees—many of whom are part-time employees.

Covid hit us around mid-March of last year. We did not do any molecular, so we scrambled to find reference partners and to get our own molecular equipment. A lot of our Covid testing has gone to other partners, such as Unity Clinic in Searcy and Natural State Laboratories in Little Rock.

How many Covid-19 PCR tests is Conway Regional Laboratory doing per day?

We purchased a Cepheid GeneXpert instrument and a Biofire FilmArray, both of which perform respiratory panels that include Covid, and started in-house Covid-19 PCR testing in September 2020. We are capable of performing 180 Covid PCR tests in a 24-hour period. At certain points we were doing that many, but that has let up in the last few months. A month ago, we were probably sending 200 specimens to Searcy and running 100 to 150 a day at Conway. Now, we are probably sending 100 a day to Unity and Searcy and performing 75 to 100 in-house.

Are you offering antibody testing? Is there a demand?

Yes—total antibody. As time goes by, people will want to know if they have responded to the vaccination. We are using a Roche test and performing about 15 per day.

Are you performing antigen testing for Covid-19?

We are doing some antigen testing, but a lot of our providers want that reflexed to a PCR if it's negative. The false negatives on antigen testing run 3% to 8%.

Are there any particular areas of non-Covid-19 testing that are still depressed?

Arkansas went through about six weeks where we did not do elective surgeries, but eventually those came back (with a negative test prior to the surgery). We are pretty much back to where we were before Covid hit.

Are you experiencing any shortages in staffing?

Yes, we have four to five open positions. The lab workforce is aging, and some people who were close to retirement went ahead and retired. We do have strong relationships with the medical technology program in the state, but it's not enough to fill our openings.

Have your laboratory staff been vaccinated?

By and large, yes—about 85% have been. There has been some reluctance by childbearing women.

Highlights From ACLA Annual Meeting

The American Clinical Laboratory Association (ACLA) held its 50th Annual Meeting virtually this year on March 10-11. More than 288 lab professionals attended the live video sessions. Here are some highlights.

The Need for Broad Lab Participation in PAMA Rate Surveys

“As we continue to navigate the pandemic—and as cuts to lab services are set to begin again in 2022—it’s critical that Congress build on the bipartisan success of the LAB Act and remedy PAMA so that the Clinical Laboratory Fee Schedule will be truly market-based and representative of the full range of laboratories serving patients throughout the country,” noted ACLA President Julie Khani.

Labs are scheduled to submit their private-payer payment data from first-half 2019 to CMS in 2022. CMS will use this data to calculate new CLFS test code rates for 2023-2025. The worry is that limited survey participation from hospital outreach labs will once again skew the CLFS rate calculations toward the lower rates paid to the nation’s biggest commercial labs.

Changes to Stark Law and Anti-Kickback Statute

A session on recent changes to the Stark Law (Stark) and the anti-kickback statute (AKS) was led by three healthcare attorneys: Jane Pine Wood, Chief Legal Counsel for Bio-Reference Laboratories, Karen Lovitch, Chair of the Health Law Practice at Mintz Levin, and Kimberly Brandt, Partner at Tarplin, Downs & Young. Changes to the Stark and AKS became effective Jan. 19, 2021, and provides clinical labs with more flexibility in many of their client arrangements.

Among key changes affecting clinical labs:

- **Provision of collection supplies.** Under the Stark Law, the provision of supplies to physicians that are “used solely” to collect, transport, process or store specimens are not considered remuneration. However, “surgical” items—such as reusable aspiration and injection needles and snares—historically have been carved out from this exception and have been considered remuneration. Under the changes, CMS now will look at how an item is being used to determine if it qualifies for the exception. This will include comparing the number of items being provided to the physician office and the number that are actually sent to the lab for processing.
- **Limited Remuneration.** There is a new exception for certain limited remuneration paid to a physician up to an annual limit of \$5,000. This applies to any type of remuneration provided to a physician in return for the physician’s provision of items or services, such as professional services arrangements, staffing arrangements and equipment/space leases. Brandt noted that the impetus for adding this new exception was the numerous non-abusive arrangements disclosed through the CMS Voluntary Self-Referral Disclosure Protocol. These arrangements do not have to be set in advance.
- **Commercially Reasonable.** Under the changes, “commercially reasonable” means that a particular arrangement furthers a legitimate business purpose AND makes sense as a means to accomplish the parties’ goals. Wood noted that this is especially relevant for a new laboratory that opens a patient service center in a physician-office building but is not profitable for a year or two. Such an arrangement would now be considered “commercially reasonable” even though it is not initially profitable.

The physician self-referral final rule is available at <https://www.federalregister.gov/documents/2020/12/02/2020-26140/medicare-program-modernizing-and-clarifying-the-physician-self-referral-regulations>.

The Pandemic's Effect on Technology Adoption

At the ACLA meeting, a panel of four laboratory executives discussed the pandemic and how it has greatly accelerated the use of various healthcare technologies.

Mohamed Salama, MD, Chief Medical Officer at Mayo Clinic Laboratories, “Digital pathology and the digitization of data in general will enable AI....I would not be surprised, in five years, if the way image-based pathologists practice is completely different and revolutionized....Once you digitize the data, you can link and add value from other laboratory data and you might enable medical decisions to be made that avoid, for example, invasive procedures or biopsies. The payers are going to recognize this and become smarter in helping to drive this.”

Dorothy Adcock, MD, Chief Medical Officer and Senior Vice President at LabCorp Diagnostic Laboratories, “It’s greatly advanced the move to digital pathology by a number of years at least. The idea of digitizing and what you can apply to that in regards to quality...counting mitotic figures, or looking at intensity of staining, it’s just so much more objective. Those that have implemented digital pathology have found more efficiency in terms of doing things more rapidly and pulling up images.”

Robin Harper Cowie, Chief Financial Officer at Biodesix, said that prior to the pandemic, “We were starting to see more telehealth, or Zoom health, as an option, particularly in rural areas where a patient would need to travel. But I think the Covid pandemic really accelerated this shift....Physicians and hospitals are relying so much more on telehealth to interact with their patients without having them come in physically. It might have taken 10 years to get to where we are now....We also see a significant increase in mobile phlebotomy....This was used somewhat prior to the pandemic, but as patients are not coming into hospitals, it has become a critical method to be able to get testing samples collected.”

Laura Housman, MPH, Head of Access, Outcomes and Population Health at Exact Sciences, noted that “There have always been care gaps in colorectal cancer screenings, but these got majorly exacerbated in 2020 due to the pandemic....Acuity data has shown that of the typical 9.5 million colorectal cancer screenings performed annually in the United States, about 72% of them were not occurring in 2020. And that has a downstream impact on missed cancers and poorer clinical outcomes.”

ACLA Elects New Board Members

Separately, ACLA announced the election of its new Board of Directors for 2021-2022. William Morice II, MD, PhD, Chair of the Department of Laboratory Medicine and Pathology at Mayo Clinic, will become ACLA Board Chair, replacing Douglas VanOort, Chairman and CEO of NeoGenomics. Jerry Hussong, MD, CEO of Sonic Healthcare USA was re-elected Vice Chair and John Kolozsvary, CEO of Joint Venture Hospital Laboratories, was re-elected Treasurer.

Labcorp To Use PathAI For Cancer Drug Trials

Labcorp and PathAI (Boston, MA) have announced an agreement under which LabCorp’s drug development division will use PathAI’s artificial intelligence algorithms in prospective clinical trials of cancer and other diseases. The new agreement follows Labcorp’s minority stake investment in PathAI in 2019 and their collaboration to accelerate the use of AI-assisted digital pathology.

Ibex Raises \$38 Million To Market Its AI Programs

Ibex Medical Analytics (Tel Aviv, Israel) has raised \$38 million from a series B financing round led by Octopus Ventures and 83North. Also participating in the round was aMoon, Planven Entrepreneur Ventures and Dell Technologies. Ibex has now raised a total of \$52 million since its launch in 2016. Ibex plans to use the funds to help market its AI algorithms for digital pathology to labs in North America and Europe.

Spotlight Interview with GENETWORx Labs' William Miller

GENETWORx Laboratories (Glen Allen, VA) is a subsidiary of Recovery Centers of America, which operates 16 addiction treatment facilities in six states (IL, IN, MA, MD, NJ and PA). Prior to the start of the pandemic, GENETWORx had specialized in gastrointestinal, respiratory virus and toxicology testing. *Laboratory Economics* recently spoke with GENETWORx CEO William Miller about his lab's jump into Covid-19 PCR testing and its strategy for after the pandemic ends.



When did GENETWORx start Covid-19 PCR testing?

Before the pandemic, our lab already had a well-established respiratory virus testing program, so we were able to add Covid-19 PCR testing fairly quickly. We ran our first test on March 23, 2020, and initial volumes averaged a few hundred tests per day. Our biggest wave of demand occurred in December and January when we averaged as many as 55,000 to 60,000 tests per day. We're currently performing about 35,000 Covid-19 PCR tests per day.

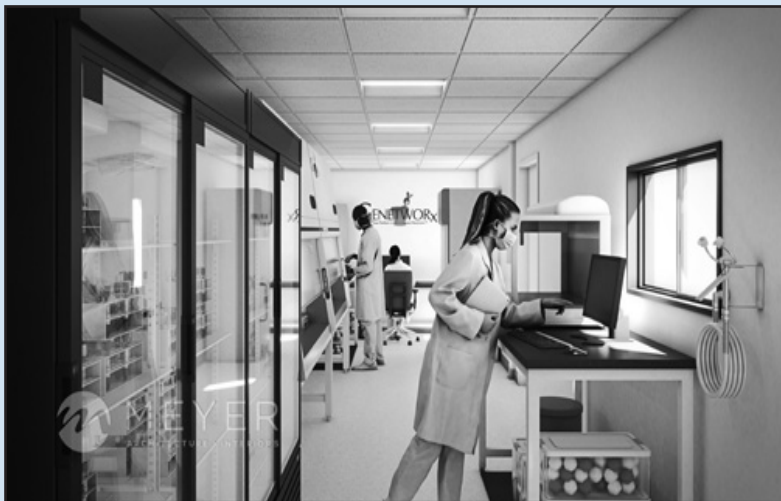
We've now performed a total of more than four million tests and have scaled up from 60 employees to nearly 700 employees over the past 12 months. Turnaround time at our main lab in the Richmond area is under 48 hours. Our primary instrument systems are LGC IntelliQube and Bio-Rad.

Can you describe your mobile labs?

In order to lower turnaround times, we have opened two mobile labs for Covid-19 PCR testing. The first was opened in December in Woodbridge, New Jersey, followed by another in Phoenix, Arizona. A third is in the process of being opened in Florida.

Each mobile lab consists of 2 tractor trailer units with combined space of approximately 1000 square feet. These labs have obtained CLIA certification through our primary lab in Virginia and each contains all the equipment necessary to perform Covid-19 PCR and antigen testing. Max daily volume at each mobile lab is 3,500 PCR tests.

Inside GENETWORx Mobile Lab



Each mobile lab has about 40 employees and runs 24/7, primarily serving universities, colleges and employers seeking to get their employees and students back to work and in the classroom. Turnaround times average less than 16 hours and can be as low as 4 hours.

Have your employees been vaccinated?

Lab employees were included in the first wave of vaccinations in Virginia and the majority of our employees have gotten both shots.

As the pandemic recedes, what will you do with all the PCR test capacity you have built up?

Over the long term, Covid testing will be offered as a part of a panel for respiratory viruses. We also see opportunities in next-gen sequencing for hereditary cancer and somatic mutations. We'll also expand our PCR test menu for other respiratory viruses, infectious diseases and women's health.

California Finalizes Medi-Cal Rate Cuts For Some Lab Tests

The California Department of Health Care Services (DHCS) has finalized reimbursement cuts for 19 high-volume lab and anatomic pathology test codes on its Medi-Cal fee-for-service rate schedule effective retroactively to July 1, 2020. The rate cuts were based on a survey of private payer rates paid to labs and pathology groups in 2018.

Initial preliminary survey results showed about 60 different test code rates being reduced (see *LE* August 2020). DHCS says that there was a decrease in the number of codes affected by the survey review because of a correction to the initial weighted rate methodology calculation. The DHCS rate methodology for lab and pathology services is the lesser of the weighted survey rates or 80% of current Medicare rates.

The DHCS survey was completed by only 118 independent labs and 14 hospital labs. However, it provides a glimpse into potential outcomes when CMS resets the Medicare CLFS in 2023 based on private-payer rates paid to labs in 2019. The results from the latest California survey suggest that big Medicare rate cuts for key toxicology codes (e.g., 80305, G0452 and G0453) are likely in 2023.

The Medi-Cal program's next triennial survey-based rate calculation for lab and pathology test codes will be based on third-party payer rate data collected from calendar year 2021, reported in 2022 and effective in July 2023.

Sample of Final Medi-Cal Lab and Pathology Rates Effective July 1, 2020 through June 30, 2021

CPT Code	Description	Old Medi-Cal Rate	New Medi-Cal Rate	% Chg	2021 Medicare National Rate	New Medi-Cal as Percent of Medicare
80305	Drug Test(s) Presumptive	\$11.97	\$9.98	-17%	\$12.60	79%
82172	Assay of Apolipoprotein	13.15	12.96	-1%	21.09	61%
82270	Occult Blood Feces	2.92	2.48	-15%	4.38	57%
82962	Glucose Blood Test	2.00	1.57	-22%	3.28	48%
83789	Mass Spec Qual/Quan	16.34	16.28	0%	24.11	68%
86677	Helicobacter Pylori Antibody	12.95	12.42	-4%	16.85	74%
87653	Strep B DNA Amp Probe	30.52	24.68	-19%	35.09	70%
88108	Cytopath Concentrate Tech	28.92	22.07	-24%	63.85	35%
G0482	Drug Test Def 15-21 Classes	132.82	126.22	-5%	198.74	64%
G0483	Drug Test Def 22+ Classes	172.18	160.47	-7%	246.92	65%

Source: California Department of Health Care Services

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Toxicology Labs Average \$458 Per Medicare Patient

The top 25 independent toxicology lab companies performed an average of 4.5 allowed tests and received \$458 of payments per Medicare patient served in 2018, according to data analyzed by *Laboratory Economics* from the Medicare Part B program.

The top independent toxicology lab was Aegis Sciences (Nashville, TN) which received a total of \$48.6 million of Medicare Part B payments in 2018. Aegis averaged 3.3 allowed tests and \$395 per Medicare beneficiary served.

Three toxicology labs were significantly above the norm in terms of average allowed tests and Medicare Part B payments per Medicare beneficiary served: Elite Diagnostics (Crown Point, IN), 46.1 tests and \$1,889; Novi Reference Laboratory (Novi, MI), 28.2 tests and \$1,693; and Total Wellness Centers (Holyoke, MA), 24 tests and \$1,640.

Top 25 Toxicology Labs by Medicare Part B Payments for 2018

Laboratory Name/Location	Number of Allowed Tests	Number of Medicare Beneficiaries Served	Total Medicare Payment Amount	Avg. Number of Tests per Beneficiary	Avg. Medicare Allowed Amount per Beneficiary
Aegis Sciences (Nashville, TN)	402,995	123,150	\$48,616,003	3.3	\$395
Millennium Health (San Diego, CA)	268,664	108,465	43,076,250	2.5	397
MD Spine Solutions (Reno, NV)	194,493	21,556	14,532,300	9.0	674
Ethos Holding Corp. (Newport, KY)	209,278	24,850	14,377,938	8.4	579
Precision Toxicology (San Diego, CA)	75,342	27,152	12,435,526	2.8	458
LabSource LLC. (Greenville, SC)	67,273	13,527	11,239,040	5.0	831
Lifebrite Labs (Brookhaven, GA)	246,622	17,700	10,593,736	13.9	599
American Institute of Toxicology (Denton, TX)	111,765	19,977	8,911,401	5.6	446
Dominion Diagnostics (N. Kingstown, RI)	87,862	19,232	8,512,833	4.6	443
American Forensic Tox Services (Huntington, NY)	65,474	17,075	6,549,047	3.8	384
Genotox Laboratories (Austin, TX)	38,627	13,012	6,235,355	3.0	479
Radeas LLC. (Wake Forest, NC)	31,818	10,802	6,021,931	2.9	557
Ameritox (Greensboro, NC)	47,045	23,274	5,917,446	2.0	254
Realtox Labs (Reisterstown, MD)	75,784	8,872	5,387,360	8.5	607
Compass Lab Services (Memphis, TN)	33,832	9,787	5,040,122	3.5	515
Drugscan Inc. (Horsham, PA)	52,831	15,475	5,004,201	3.4	323
Alere Toxicology Services (Austin, TX)	46,349	15,702	4,936,849	3.0	314
National Labs Inc. (Hayward, CA)	86,037	7,852	4,318,185	11.0	550
Parkway Clinical Labs (Bensalem, PA)	34,121	7,847	4,133,014	4.3	527
Advanta Toxicology (Tyler, TX)	30,095	7,351	4,015,664	4.1	546
Synergy Laboratories (Theodore, AL)	48,083	9,725	4,001,174	4.9	411
Total Wellness Centers (Holyoke, MA)	42,269	1,758	2,882,655	24.0	1,640
Novi Reference Laboratory (Novi, MI)	45,823	1,623	2,748,019	28.2	1,693
Elite Diagnostics (Crown Point, IN)	63,917	1,387	2,620,139	46.1	1,889
LabCorp/MedTox Labs (St. Paul, MN)	19,093	6,226	1,959,261	3.1	315
Total Top 25 Toxicology Labs	2,425,492	533,377	\$244,065,450	4.5	\$458

Source: Laboratory Economics from Medicare Provider Utilization Files for 2018

Covid Testing Spurs New Lab Boom (cont'd from page 1)

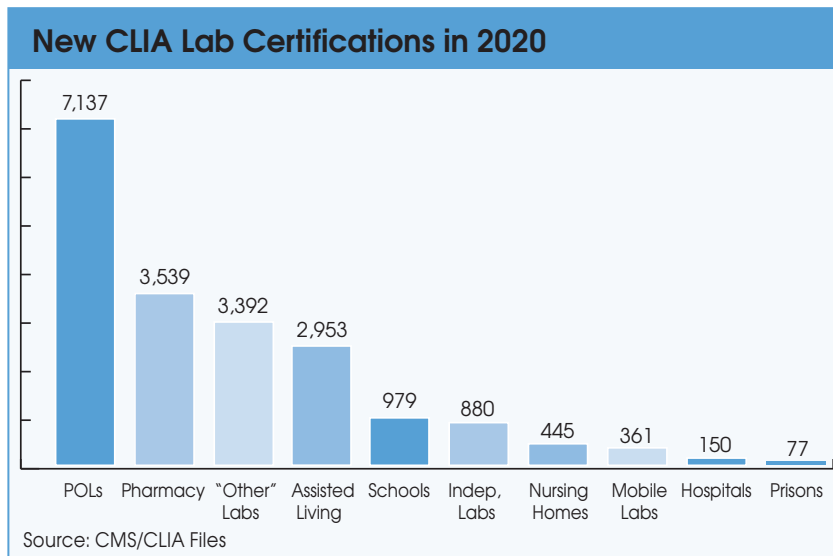
Among the categories that saw the greatest number of new CLIA lab certifications was “other” labs (3,392 new labs), which includes a large number of new labs at dental offices, substance abuse and addiction treatment facilities, sports stadiums and fire departments.

In addition, there were 979 new CLIA labs opened at schools/student health centers and 361 new mobile labs were formed.

The total number of 24,559 new CLIA labs created in 2020 is probably very much understated because during the Covid-19 public health emergency, CMS has relaxed its rules and allowed existing CLIA labs, under certain circumstances, to open additional sites without gaining new CLIA certificates, including for new labs that are not in a fixed location and labs located within a hospital campus.

Furthermore, many clinical labs popped up during the past year without obtaining an appropriate CLIA certificate. Late last year, CMS announced a crackdown on labs that were testing for

Covid-19 without proper certification. The agency said it has issued 171 cease-and-desist orders to facilities that were either conducting lab testing without CLIA certificates or performing Covid-19 testing outside the scope of their existing certification.



Enzo Founder And CEO Elazar Rabbani To Step Down

Enzo Biochem (New York City) says that Elazar Rabbani, PhD, Chairman and CEO, will remain a Director but will step down as CEO and transition to a scientific role with the company once a qualified successor is hired. Rabbani, age 77, founded Enzo and has served as Chairman and CEO since the company's inception in 1976. Enzo's Board of Directors has retained the global search firm Korn Ferry to conduct the CEO search.

In addition, Enzo has hired Gary Huff, the former CEO of LabCorp Diagnostics, to serve as a strategic consultant to the Board. Enzo has also retained Cain Brothers, a healthcare investment banking firm, to help identify, evaluate and execute strategic and commercial opportunities.

Enzo's largest shareholders, including Harbert Discovery Fund (11.7% stake) and Roumell Asset Management (5.8% stake), have been pushing Enzo to pursue a sale (see *LE*, December 2020).

Separately, Enzo reported net income of \$2.3 million in the three months ended January 31, 2021 versus a net loss of \$7.7 million in the same period a year ago; revenue was up 62% to \$31.5 million.

Enzo's clinical lab division, which serves the greater New York City area, recorded a revenue increase of 92% to \$24 million for the latest three-month period. The revenue growth was driven primarily by a nearly 65% increase in volume to 330,000 patient accessions due to demand for Covid-19 testing.

Lab Stocks Up 16% Year To Date

Twenty-two lab stocks have risen by an unweighted average of 16% year to date through March 12. In comparison, the S&P 500 Index is up 5% thus far in 2021. The top-performing lab stocks so far have been DermTech, up 65%; Myriad Genetics, up 57%; and Veracyte, up 55%. Shares of LabCorp are up 17% year to date, while Quest Diagnostics is up 2%.

Company (ticker)	Stock Price 3/12/21	Stock Price 12/31/20	2021 Price Change	Enterprise Value (\$ mill)	Enterprise Value/Revenue	Enterprise Value/EBITDA
LabCorp (LH)	\$238.71	\$203.55	17%	\$28,600	2.1	9.4
Exact Sciences (EXAS)	128.46	132.49	-3%	22,130	14.8	NA
Quest Diagnostics (DGX)	121.87	119.17	2%	19,910	2.1	8.3
Sonic Healthcare (SHL.AX)*	31.28	32.15	-3%	17,930	2.3	8.8
Guardant Health (GH)	142.96	128.88	11%	13,620	47.5	NA
Natera (NTRA)	104.04	99.52	5%	8,460	21.6	NA
Invitae (NVTA)	42.70	41.81	2%	6,810	24.4	NA
NeoGenomics (NEO)	49.23	53.84	-9%	5,560	12.5	193.8
Veracyte (VCYT)	75.73	48.94	55%	4,700	41.7	NA
CareDx (CDNA)	67.54	72.45	-7%	3,390	17.6	NA
Opko Health (OPK)	4.44	3.95	12%	3,200	2.2	20.5
Myriad Genetics (MYGN)	31.04	19.77	57%	2,480	4.5	NA
DermTech Inc. (DMTK)	53.55	32.44	65%	1,490	253.4	NA
Castle Biosciences (CSTL)	64.19	67.15	-4%	1,480	23.6	NA
Aspira Women's Hlth (AWH)	7.66	6.71	14%	843	186.7	NA
Biodesix (BDSX)	22.80	20.16	-37%	644	24.1	NA
Progenity (PROG)	4.84	5.31	-9%	278	3.5	NA
Exagen (XGN)	20.02	13.20	52%	218	5.5	NA
Enzo Biochem (ENZ)	2.86	2.52	13%	126	1.5	NA
Interpace Biosciences (IDXG)	4.64	3.14	48%	67	2.5	NA
Biocept (BIOC)	6.08	4.44	37%	67	6.2	NA
Psychedics (PMD)	7.15	5.09	40%	48	2.0	NA
Unweighted Averages			16%	\$142,051	31.9	48.2

*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

The latest analysis from the CDC estimates that only 1 out of 4.6 total Covid-19 infections have been reported (<https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/burden.html>). An alternative estimate can be based on assuming an infection fatality ratio of 0.4% compared with the number of Covid-19 deaths. Together these methods indicate that an estimated 41-46% of the U.S. population had been infected with Covid-19 as of March 13. The peak in daily new U.S. confirmed cases came in early January 2021.

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, MA, HI, VA, DC, VT, ME, CO, NM, WA) that have had the most restrictions have a weighted-average population infection rate of 37-38% and an average of 1,336 Covid-19 deaths per million.

The 10 states (IA, OK, SD, UT, ID, FL, AK, AR, MO, WI) that have had the fewest restrictions have a weighted-average population infection rate of 40-45% and an average of 1,385 Covid-19 deaths per million.

U.S. Covid-19 Statistics (as of March 13, 2021)

State	Population	Confirmed Cases	Peak Cases	% Pop that has been infected	Covid-19 Deaths	Deaths/1 mill pop
New Jersey	8,882,190	830,848	Jan. 13, 2021	43-77%	23,854	2,686
New York	19,453,561	1,768,855	Jan. 15, 2021	42-72%	49,021	2,520
Rhode Island	1,059,361	130,502	Dec. 4, 2020	57-69%	2,567	2,423
Massachusetts	6,892,503	598,859	Jan. 2, 2021	40-69%	16,580	2,406
Mississippi	2,976,149	299,887	Jan. 7, 2021	46-66%	6,883	2,313
Arizona	7,278,717	831,832	Jan. 3, 2021	53-65%	16,519	2,269
Connecticut	3,565,287	290,577	Dec. 28, 2020	37-62%	7,765	2,178
South Dakota	884,659	114,347	Nov. 27, 2020	59-62%	1,907	2,156
Louisiana	4,648,794	436,482	Jan. 6, 2021	43-61%	9,861	2,121
Alabama	4,903,185	502,711	Jan. 5, 2021	47-60%	10,299	2,100
Pennsylvania	12,801,989	966,647	Dec. 11, 2020	35-55%	24,639	1,925
North Dakota	762,062	100,847	Nov. 14, 2020	55-61%	1,455	1,909
Indiana	6,732,219	671,023	Dec. 3, 2020	46-54%	12,824	1,905
New Mexico	2,096,829	187,984	Nov. 19, 2020	41-52%	3,849	1,836
Illinois	12,671,821	1,206,172	Nov. 13, 2020	44-52%	23,163	1,828
Arkansas	3,017,804	326,499	Jan. 1, 2021	50-51%	5,437	1,802
Iowa	3,155,070	369,795	Nov. 14, 2020	51-54%	5,630	1,784
South Carolina	5,148,714	530,880	Dec. 27, 2020	47-49%	8,833	1,716
Georgia	10,617,423	1,031,713	Jan. 8, 2021	45-49%	18,164	1,711
Tennessee	6,829,174	789,652	Dec. 16, 2020	49-53%	11,639	1,704
Michigan	9,986,857	668,085	Nov. 20, 2020	31-48%	16,730	1,675

U.S. Covid-19 Statistics (as of March 13, 2021)

<i>State</i>	<i>Population</i>	<i>Confirmed Cases</i>	<i>Peak in Daily New Cases</i>	<i>Estimated % Pop infected</i>	<i>Covid-19 Deaths</i>	<i>Deaths/ 1 mill pop</i>
Kansas	2,913,314	300,213	Nov. 23, 2020	47-48%	4,863	1,669
Nevada	3,080,156	298,623	Dec. 12, 2020	45-47%	5,097	1,655
Texas	28,995,881	2,725,374	Jan. 5, 2021	43-46%	46,457	1,602
Delaware	973,764	89,911	Jan. 7, 2021	42-44%	1,496	1,536
Ohio	11,689,100	986,740	Jan. 2, 2021	39-44%	17,871	1,529
Florida	21,477,737	1,967,865	Jan. 1, 2021	42-43%	32,170	1,498
District of Columbia	705,749	42,282	Dec. 27, 2020	28-42%	1,038	1,471
Missouri	6,137,428	527,353	Nov. 10, 2020	40-41%	8,903	1,451
California	39,512,223	3,618,594	Dec. 16, 2020	40-42%	55,455	1,403
West Virginia	1,792,147	134,842	Jan. 1, 2021	35-40%	2,511	1,401
Maryland	6,045,680	391,480	Dec. 4, 2020	30-38%	8,030	1,328
Montana	1,068,778	101,556	Nov. 14, 2020	37-44%	1,392	1,302
Minnesota	5,639,632	495,208	Nov. 29, 2020	34-40%	6,805	1,207
Wyoming	578,759	55,163	Nov. 23, 2020	34-44%	691	1,194
Oklahoma	3,956,971	431,366	Jan. 10, 2021	34-50%	4,701	1,188
Virginia	8,535,519	592,214	Jan. 17, 2021	32-33%	9,961	1,167
Wisconsin	5,822,434	568,902	Nov. 18, 2020	32-45%	6,525	1,121
North Carolina	10,488,084	881,823	Jan. 9, 2021	32-39%	11,663	1,112
Kentucky	4,467,673	415,091	Jan. 6, 2021	32-43%	4,950	1,108
Nebraska	1,934,408	204,162	Nov. 16, 2020	31-49%	2,124	1,098
Idaho	1,787,065	174,943	Dec. 9, 2020	31-45%	1,909	1,068
Colorado	5,758,736	441,511	Nov. 13, 2020	30-35%	6,072	1,054
New Hampshire	1,359,711	78,074	Jan. 3, 2021	25-26%	1,195	879
Washington	7,614,893	351,763	Dec. 7, 2020	19-21%	5,184	681
Utah	3,205,958	377,492	Dec. 31, 2020	18-54%	2,017	629
Oregon	4,217,737	159,037	Dec. 4, 2020	16-17%	2,319	550
Maine	1,344,212	46,650	Jan. 2, 2021	15-16%	723	538
Alaska	731,545	57,784	Dec. 5, 2020	12-36%	302	413
Vermont	623,989	16,623	Jan. 7, 2021	10-12%	212	340
Hawaii	1,415,872	28,145	Aug. 13, 2020	9-10%	449	317
Ten most restrictive states (CA, MA, HI, VA, DC, VT, ME, CO, NM, WA)	74,500,525	5,924,625		37-38%	99,523	1,336
Ten least restrictive states (IA, OK, SD, UT, ID, FL, AK, AR, MO, WI)	50,176,671	4,916,346		40-45%	69,501	1,385
U.S. Totals	328,239,523	29,214,981	Jan. 7, 2020	41-46%	530,704	1,617

Source: *Laboratory Economics* from CDC, Worldometers.com and WalletHub.com