## LABORATORY

# economics

Competitive Market Analysis For Laboratory Management Decision Makers

which gathers state

testing data. The

late-July surge in testing came at the

height of outbreaks in the Southeast

and Sun Belt states. Meanwhile, ACLA member labs' share

of Covid-19 PCR

testing continues

to hover at around

50%, with hospitals and independent

labs performing the

other half.

### Have Covid-19 Test Volumes Peaked?

The average daily volume of Covid-19 PCR testing performed in the United States was 720,000 in the week ended August 14, down from the average of 823,000 tests per day in late July, according to the Covid Tracking Project,



PC Rates For Key Pathology Services To Get 12% Cut

Medicare professional component (PC) reimbursement rates for most highvolume pathology services will be cut by 12% next year, according to the newly released Proposed Medicare Physician Fee Schedule (MPFS) for 2021. For example, the 2021 Medicare rate for the PC of CPT 88305 is proposed to be cut by 12% to \$34.52, while the TC will remain the same at \$32.26. Overall, the proposed global rate for CPT 88305 will decline by 7% to \$66.78. The reductions are the result of budget neutrality requirements that offset the cost of major rate hikes given to evaluation and management (E/M) services paid to primary care physicians. *Continued on page 8*.

### Medi-Cal Seeks Approval To Slash Lab Rates

California's Department of Health Care Services (DHCS) has completed its Clatest private-payer lab rate survey and is seeking federal approval to lower Medi-Cal fee-for-service (FFS) rates for more than 60 high-volume lab and pathology services (effective retroactive to July 1, 2020 upon federal approval). DHCS estimates that the proposed rate cuts will save Medi-Cal approximately \$12 million annually from the \$212 million per year it currently spends on FFS payments for lab and pathology services. If finalized, Medi-Cal rates for high-volume lab and pathology codes will fall to a range of as little as 17% current Medicare rates to a maximum of no more than 80%. *Continued on page 2*.

### CONTENTS

#### HEADLINE NEWS

Have Covid-19 PCR Test
Volumes Plateaued? 1
Professional Rates for Key
Pathology Codes
Set To Fall 12%1, 8-9
Medi-Cal Seeks Approval
To Slash Rates1-4

#### SPOTLIGHT INTERVIEWS

#### REIMBURSEMENT

Proposed Medicare Rate
Changes for Key
Pathology Codes9

#### FINANCIAL

LabCorp Mid-Year Results	10
Quest Diagnostics	
Mid-Year Results	11
Lab Stocks Up 42% YTD	12

#### STATISTICAL ADDENDUM

NYC Covid-19 Stats	13
Arizona Covid-19 Stats	14
Sweden's Covid-19 Stats	15
Trends in CA, TX and FL	16
Worldwide Covid-19 Stats	17

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#### Medi-Cal Seeks Approval To Slash Lab Payments (cont'd from page 1)

2

California's Medi-Cal lab fee schedule has been pegged to private-payer rates since 2015. The new proposed rates are based on DHCS's fourth private-payer rate survey, which required approximately 300 independent labs, hospitals and pathology groups in California to submit their 10 lowest private-payer rates received in calendar year 2018 for approximately 270 high-volume lab and pathology CPT codes.

Only 132 providers actually wound up submitting their pricing data, including 14 hospital labs and 118 independent labs. DHCS has the authority to suspend providers that don't report. However, no lab suspensions have occurred to date.

DHCS took the submitted private-payer pricing data, threw out any rates higher than 80% of the current national Medicare rates, and then calculated its proposed Medi-Cal rates based on a weighted average of the remaining private-payer survey data.

The most severe rate reductions that will occur as a result of the latest survey include an 80% reduction in the Medi-Cal rate for CPT 84402 (Free Testosterone) to a proposed rate of \$4.45. If finalized at \$4.45, then Medi-Cal will be paying a rate equivalent to only 17% of the current Medicare rate of \$25.47 for CPT 84402. This proposed rate is so low that it suggests a calculation error, notes *Laboratory Economics*.

Other codes with proposed Medi-Cal rate reductions so extreme that they may be erroneous include 84681 (C-Peptide), equivalent to 22% of Medicare; CPT 88307 (Surgical pathology-Level V), equivalent to 27%; and 88312 (Special Stains Group 1), equivalent to 25%.

СРТ		Current Medi-Cal	Proposed Medi-Cal		2020 Medicare	Proposed Medi-Cal as Percent of
Code	Description	Rate	Rate	% Change	Rate	Medicare
82270	Occult Blood Feces	\$2.92	\$2.48	-15.1%	\$4.38	57%
82962	Glucose Blood Test	2.00	1.57	-21.5%	3.28	48%
84402	Free Testosterone	22.68	4.45	-80.4%	25.47	17%
84443	Thyroid Stim Hormone (TSH)	14.76	11.20	-24.1%	16.80	67%
84480	Assay Triiodothyronine (T3)	12.59	8.82	-29.9%	14.18	62%
84681	Assay of C-Peptide	17.83	4.53	-74.6%	20.81	22%
85025	Automated Hemogram	6.75	3.33	-50.7%	7.77	43%
86038	Antinuclear Antibodies (ANA)	10.63	6.47	-39.1%	12.09	54%
86141	High-Sensitivity CRP	11.19	7.16	-36.0%	12.95	55%
87389	HIV-1 Ag W/HIV-1 & HIV-2 Ab	20.26	14.04	-30.7%	24.08	58%
87502	Influenza DNA Amp Probe	77.00	52.98	-31.2%	95.80	55%
87631	Resp Virus 3-5 Targets	61.07	45.10	-26.2%	142.63	32%
87633	Resp Virus 12-25 Targets	388.39	139.79	-64.0%	416.78	34%
88172	Cytp Dx Eval FNA 1st Each Site	28.29	25.58	-9.6%	57.02	45%
88184	Flowcytometry/ TC 1 Marker	42.18	32.67	-22.5%	68.21	48%
88189	Flowcytometry/Read 16 & >	69.18	30.58	-55.8%	88.78	34%
88307	Surgical pathology (Level V)	87.64	76.30	-12.9%	281.50	27%
88312	Special Stains Group 1	32.83	26.78	-18.4%	107.19	25%
G0482	Drug Test Def 15-21 Classes	132.82	126.22	-5.0%	198.74	64%
G0483	Drug Test Def 22+ Classes	172.18	160.47	-6.8%	246.92	65%
Source: C	alifornia DHCS					

#### Sample of Proposed Medi-Cal Lab & Pathology Rate Changes

#### California Clinical Lab Assn. Seeks Elimination of 80% Cap

In a letter to DHCS, the California Clinical Laboratory Association (CCLA) said that now is not the time to be substantially lowering reimbursements to labs which are playing a critical role in the fight against Covid-19. CCLA is supporting a bill (AB 1327) from California Assemblywoman Cottie Petrie-Norris that would eliminate the 80% of Medicare cap on Medi-Cal FFS rates for lab and pathology services. This bill was first introduced in February 2019.

CCLA attorney Kristian Foy says that there is no justification for the 80% cap given that Medicare CLFS tests were reduced by 10% per year between 2018 and 2020 under PAMA. Removal of the cap might allow Medi-Cal rates for some lab and pathology test codes to rise to up to 100% of current Medicare rates. Foy says that the 80% Medicare cap applied to California's pricing data survey is undermining the purpose behind developing Medi-Cal's California-specific market-based rates.

Furthermore, Quest Diagnostics, which is the biggest Medi-Cal lab provider (see page 4), has argued that national Medicare rates should not dictate rates in California because the implementation of PAMA relied on flawed and incomplete survey data. Other organizations supporting the Petrie-Norris bill include the California Association of Public Health Lab Directors, California Medical Association, LabCorp and Planned Parenthood Affiliates of California.

Finally, CCLA is also asking that the Assembly Bill 97 (AB 97) 10% reduction to Medi-Cal lab and pathology rates be eliminated. The AB 97 10% payment reduction, which applies to most Medi-Cal providers, was enacted during the California's budget crisis of 2011 and has no sunset date.

A decision from CMS on the current proposed Medi-Cal lab and pathology rates is expected soon. The next DHCS private-payer data survey is scheduled to occur in 2022, and will be used to establish the July 1, 2023, Medi-Cal lab and pathology rates.

Meanwhile, Medi-Cal's transition to using private-payer lab rates has helped it reduce its expenditures on lab testing for its two million fee-for-service (FFS) members from \$314 million in 2012 to \$212 million in 2019. Medi-Cal lab expenditures have also been tempered by a steady movement toward Medi-Cal managed care plans. Managed care plans are paid on a capitated basis,



and they manage member care and negotiate and establish their own rates with their contracted providers. There are currently 10.3 million Medi-Cal members covered by managed care plans.

#### Medi-Cal Rates for Covid-19 Testing

Medi-Cal reimbursement rates for the new Covid-19 testing codes, including diagnostic testing (U0003 and U0004) and antibody testing (86328 and 86769), has been established at 100% of corresponding Medicare rates. In addition, the AB 97 10% reduction has been waived for the duration of the coronavirus crisis. Upon expiration of the public health emergency or national emergency, Medi-Cal rates for these codes will be lowered to 80% of Medicare and the AB 97 10% reduction will be applied.

#### Top 20 Medi-Cal Laboratories

4

The largest Medi-Cal lab provider is Quest Diagnostics, which received \$32.5 million of Medi-Cal FFS payments in 2019, up 10.3% from \$29.4 million in 2018, according to data from DHCS.

Planned Parenthood, which tests for sexually transmitted diseases, received \$29.6 million, up 19.8% from \$24.7 million in 2018.

The Genetic Disease Screening Program (GDSP) of the California Department of Health is the third largest, with \$27.6 million, down 6.5% from \$29.5 million in 2018. The Genetic Disease Screening Program provides prenatal and newborn testing services to Medi-Cal recipients.

LabCorp received \$10.3 million of Medi-Cal payments in 2019, up 16.6% from \$8.8 million in 2018.

The fastest-growing laboratory was Regents of the University of CA (aka UCLA Outreach Lab), where Medi-Cal payments jumped by 180% to \$3.5 million in 2019.

In total, the top 20 lab organizations collected \$135.1 million of Medi-Cal lab test payments for FFS patients in 2019, up 6.7% from \$126.6 million in 2018.

Provider	2019 Reimbursements Paid (FFS Only)	2018 Reimbursements Paid (FFS Only)	% Change
Quest Diagnostics	\$32,469,925	\$29,430,089	10.3%
Planned Parenthood	29,634,204	24,728,274	19.8%
CDPH Genetic Disease Branch	27,573,854	29,480,888	-6.5%
LabCorp	10,254,357	8,797,775	16.6%
Regents of the University of CA/UCLA Outreach	3,522,142	1,259,663	179.6%
Dignity Health	3,405,027	3,254,562	4.6%
Latara Enterprise (dba Foundation Laboratory)	3,300,925	3,237,767	2.0%
Childrens Hospital of Los Angeles	3,052,988	2,453,432	24.4%
Biological Laboratory Inc.	2,561,679	2,685,415	-4.6%
Family Planning Associates	2,531,898	2,675,343	-5.4%
Loma Linda University	2,443,874	2,180,461	12.1%
Alpha Clinical Lab Inc.	2,297,336	2,727,436	-15.8%
Santa Clara Medical Center	2,147,865	1,340,348	60.2%
Primex Clinical Labs	2,123,575	2,202,512	-3.6%
Whitefield Medical Labs	1,923,420	3,170,842	-39.3%
Medical Diagnostic Laboratory	1,812,697	2,466,299	-26.5%
County of San Bernardino	1,347,548	1,308,036	3.0%
Physicians Immunodiagnostic Lab	1,342,373	1,574,914	-14.8%
BioCorp Clinical Lab	1,310,422	1,643,948	-20.3%
CHLAMG-Pathology	1,237,862	NA	NA
Total for Top 20	135,056,109	126,618,004	6.7%
300+ other labs	77,428,853	80,037,507	-3.3%
Grand Total, all Medi-Cal labs	\$212,484,962	\$206,655,511	2.8%

#### Top 20 Medi-Cal FFS Laboratories in 2019

Source: California Dept. of Health Care Services

### Spotlight Interview with Sonora Quest CEO Dave Dexter

**S**onora Quest Laboratories, a joint venture between Banner Health (Phoenix) and Quest Diagnostics, recently moved into a new 250,000-square-foot facility and is quickly ramping up testing for Covid-19. SQL provides testing to 20 hospitals within the Banner Health-care System. *Laboratory Economics* recently caught up with CEO Dave Dexter to discuss the pandemic and its effect on the lab.



The governor declared an emergency on March 11, and Sonora Quest was in the second wave of labs offering testing. We began offering testing on two Roche cobas 8800's on March 17.

#### What happened to your non-Covid testing volumes in March and April?

Our volume fell off a cliff in March and April. We saw nearly a 40% decline across the board in our core business. Before we ramped up on Covid-19 PCR testing, I put Sonora Quest into sustainability mode, which has four major pieces: 1) retain cash; 2) control all variable expenses; 3) no layoffs; and 4) invest heavily in Covid-19 testing. In May we began to ramp PCR and antibody testing. We partnered with Roche and Hologic for PCR testing and with Euroimmun for antibody testing.

#### What kind of supply chain issues are you facing?

We would love to buy more reagents and instruments from Roche and Hologic, but we can't. They can't make them fast enough, and their supply chains aren't likely to be able to meet demand until early next year.

#### What were your initial PCR Covid-19 testing volumes?

In April we were running at only 20% of our Covid-19 PCR testing capability. The initial CDC and state guidelines prioritized testing for emergency departments, inpatients, health care workers and first responders, but not for residents of long-term care (LTC) facilities. We also were not allowed to test the worried well. So, in April we were underutilized. I disagreed with the fact that long-term care was left out of the prioritized group.

I reached out to the president of the Arizona Healthcare Association (AHCA) to partner with us to put together a long-term testing plan for LTC residents. We partnered with hC1 to develop a dashboard that would enable the Arizona Department of Health Services (ADHS), county health departments and individual skilled nursing facilities to manage the safety of their residents with PCR and antibody testing. In May, we began testing residents of 146 LTC skilled nursing facilities. The utilization of PCR testing then began increasing rapidly.

#### What happened after lockdown restrictions started to ease?

When the governor relaxed the stay at home order, everyone thought the virus would die in the summer heat. On Memorial Day, our positivity rate was 4.5%, but it started increasing each week after that. We have been as high as 26%. We have started to taper off and positivity is currently down to 14%.

I thought PCR demand would fall off in June and the antibody demand would increase, but the opposite happened. We couldn't keep up with demand with our two Roche instruments running full bore. We began using our Hologic Panther instruments. Between Roche and Hologic, we got our capacity to 10,600 PCR tests per day, but we still couldn't keep up because we were getting orders for 14,000 tests per day. Our IT department quickly built reverse interfaces with Quest Diagnostics so that we could offload to each other.

#### How did you ramp up Covid-19 PCR test volumes to meet demand?

We developed a plan to get up to 15,000 tests per day, which we presented to the Banner senior management and ADHS on June 19, but they said we needed to get to 60,000 tests per day. I had an idea to use open platforms if I could get a vendor to provide enough reagents. I called the CEO of Euroimmun and presented "Operation Catapult" with the goal of adding eight new Covid-19 analyzer lines.



#### Dave Dexter

Euroimmun is owned by Perkins Elmer. Perkins Elmer has instruments that can be used as an open platform, and we also partnered with Analytik Jena for PCR instruments. They called me the next day, on June 21, and we made a handshake deal for 10 million tests. These vendors sent us \$8 million of instrumentation and \$2 million of reagents, all without a purchase order. We also secured 1 million collection kits. By July 4, we had the first two lines arriving. Next, I persuaded ADHS for \$2 million in capital funding; they had to have a vested interest in Operation Catapult. I then requested \$6 million in emergency capital from the SQL board of directors and received immediate approval. All of this took place in eight days.

We brought the Perkin Elmer team in and began the task of hiring 215 people. To scale something like this is prodigious, and the plan was aggressive. We agreed to install the lines in one-third of the normal time. At the same time, the federal government started rerouting reagents for our other platforms, which lowered our maximum throughput from 10,600 to 6,000 per day. At one point we had a backlog of 65,000 tests.

We have made a commitment to scale to 60,000 tests per day by August 31. It is complicated to bring up multiple lines so quickly. Currently, we have three additional lines that have been validated and are fully operational. A fourth line is currently in validation and lines 5 and 6 are being installed. Each line has capacity for 6,000 Covid-19 PCR tests per day.

#### What are turnaround times like for Covid-19 PCR testing?

We are not quite on schedule, but we are nearly there. Our backlog is down to zero. Our commitment to Arizona is we are going to get 24-to-48-hour turnaround time by end of August because we need to enable contact tracing. We have catapulted ahead of demand in Arizona; our PCR turnaround time (TAT) is now 24 hours subject to demand, but we state 1 to 3 day TAT until August 31, at which time it will be 24 to 48 hours. For prioritized groups, our turnaround is currently 17.6 hours.

#### What are your volumes for antibody testing?

We can do about 7,500 per day, and we are averaging 3,000 per day. We don't have the demand. The demand is low because everybody wants to know if they have the virus, not if they have had it. We can ramp to 20,000 antibody tests if needed. With the high virus prevalence in Arizona, the Covid-19 antibody positivity rate has risen to 14%.

#### What happened to your non-Covid-19 testing?

We were projecting to lose millions of dollars in May, but with the ramp up of Covid-19 PCR and antibody testing, we have remained profitable even with the core business down. We had a huge shortfall in March and April, with our core business down about 40%, but we made it up entirely in May and June. Overall, our volumes were up by more than 35% in June and July, compared with a year ago. If we get to 60,000 tests per day, the numbers will go off the charts. So far, we are beating our revenue and margin targets for the year.

#### What do you think the long-term effect on Sonora Quest will be?

It depends on where we are a year from now. Rapid tests will be improved and more readily available. Nobody knows what's going to happen with price. We don't have line of sight into how effective a vaccine will be. Will the virus mutate? I think the answer is yes. We are focused on meeting demand, but our testing capacity will create a 'safety net' if we do get a second wave later. Long term, SQL is very well positioned.

#### What do you see as the impact on the lab industry overall?

That remains to be seen. I do think there will be more consolidation in the industry, which will benefit Quest and LabCorp. Most major insurance contracts are going dual source. Data analytics is going to play a huge role in the future, and Sonora Quest is a leader in that area. We just did a deal with an insurance company on data analytics, and we're close to doing another major deal on analytics with another insurer.

### Spotlight Interview With Lenco's Robert Boorstein

Lenco Diagnostic Laboratories (Brooklyn, NY) is one of New York City's largest independent full service reference laboratories. Lenco has more than 300 employees and operates a CAP-certified laboratory in Brooklyn as well as 21 PSCs throughout New York City. Below Lenco's Medical Director Robert Boorstein, MD, PhD, provides an update on Lenco and his thoughts on Covid-19.



Robert Boorstein, MD, PhD

#### When did Lenco begin PCR-based Covid-19 testing?

We launched Covid-19 PCR testing on March 19 with the Hologic Panther Fusion and immediately began testing for local hospitals and nursing homes. We've consistently been reporting 2,000 tests per day, operating 24 hours per day, seven days per week. Our turnaround time for results is currently about 2 days from specimen pickup and we're seeing average positivity rates of approximately 1.5%.

#### How is the current Covid-19 testing supply situation?

Everything related to Covid-19 testing remains in short supply, including test reagents, swabs and collection tubes, pipette tips and nucleic acid extraction kits. Typically, Invitro Diagnostic (IVD) vendors would manage all the related testing supplies for their lab customers, but many manufacturers are having their own supply chain problems, so labs are forced to find and buy many components on their own.

#### Will pooled testing for Covid-19 help alleviate shortages?

Combining samples from multiple low-risk patients in a single test may help stretch limited testing supplies. We're looking into pooled testing but have not pulled the trigger. I'm somewhat skeptical that detection levels for pooled testing can match single sample tests. There are also a number of logistical issues. Lab information systems are not designed for pooled samples and reimbursement questions have not been resolved yet.

#### Which Covid-19 antibody test is Lenco doing and how is the demand?

We started in mid-April with Diazyme, which had one of the early relatively high-throughput systems on the market. We then shifted to Diasorin since we had a large installed base of Liaison analyzers, and now we have shifted to Beckman Coulter because our largest installed base of immunoassay analyzers are from Beckman. We are currently performing about 1,400 to 1,500 antibody tests per day with the greatest demand coming from routine medical visits. We are currently averaging about 15% to 20% positive on our IgG Covid-19 serology tests.

#### What are Medicaid and the private insurers paying for Covid-19 testing?

New York Medicaid has matched the national Medicare rate of \$100 for high-throughput Covid-19 PCR-based tests (U0004). And we are working hard to see that private insurers and nursing homes maintain the \$100 per test pricing as well. Our published cash price is also \$100.

Similarly, New York Medicaid has established a rate of \$42 for antibody testing (CPT 86769) — the same as the national Medicare rate. However, some managed Medicaid plans and private insurers have not matched this rate and are paying as little as \$16. In addition, private insurers are generally only reimbursing for one antibody test per patient even when labs are testing for both IgG and IgM.

#### Have Lenco's non-Covid-19 test volumes rebounded?

Our routine test volumes started dropping in early March and by late March were down roughly 80% to 90%. At one point, our laboratory and management was very concerned about how we were going to make payroll. Our ability to get Covid testing up and running quickly helped offset initial routine volume declines.

Currently, many of our testing categories have rebounded from the lows in March and April. Overall, while not all testing is back to pre-Covid levels, our accession volumes have roughly doubled versus last year. And the expectation is that many of the new hospital and nursing home clients we signed on for Covid-19 testing will remain clients once this is over.

#### Can a person who has recovered from the coronavirus, catch it again?

There is no good evidence that indicates that people who have had Covid-19 can get it again.

#### After a severe outbreak in March-May, New York City's number of Covid-19 cases, hospitalizations and deaths have significantly declined. What are the chances of a second outbreak in New York City this fall?

With social distancing, and the current degree of seropositivity (15% to 20%), the chance of another outbreak seems low. But I would doubt that this degree of seropositivity is sufficient to allow "normal" subway ridership, restaurant and bar openings, sporting events, etc. without ongoing social distancing and mask wearing.

#### What are your thoughts on the potential for a safe and effective vaccine for Covid-19?

An impressive amount of resources is being put into vaccine development. And the FDA has said a Covid-19 vaccine must work in at least 50% of patients before it will approve the shot. So the real question is will people feel safe with a vaccine that reduces their risk of infection by 50%? Would this be enough to make you feel safe at a crowded Yankees game or restaurant without wearing a mask? Getting things back to normal might be a challenge even with a vaccine.

#### PC Rates For Key Pathology Services To Get 12% Cut (cont'd from p. 1)

Overall, CMS estimates that the new rates will reduce Medicare reimbursement to pathologists by 9% in 2021, while technical component reimbursement to pathology labs will fall by 5%. Among the other specialties hurt by the redistribution of funds to primary care physicians include anesthesiology (-8%), emergency medicine (-6%), general surgery (-7%), infectious disease (-4%) and radiology (-11%). Specialties benefiting include endocrinology (+17%), family practice (+13%), hematology/oncology (+14%), nurse practitioner (+8%) and rheumatology (+16%).

#### Immunohistochemistry

The global rate for CPT 88342 (IHC, first stain procedure) is proposed to decrease by 7% to \$99.68; professional interpretation down 12% to \$32.26; technical component down 4% to \$67.42.

The global rate for CPT 88341 (IHC, additional stain) is proposed to decline by 7% to \$88.07; professional interpretation down 12% to \$26.13; technical component down 4% to \$61.94.

#### Molecular Pathology

One of the few bright spots in the proposed MPFS for 2021 is a recalculation of the rate for Molecular Pathology Interpretation (HCPCS code G0452). The current rate of \$19.13 is proposed to more than double to \$42.91 in 2021.

#### The Clinical Laboratory Fee Schedule

An amendment (sec. 3718) to the CARES Act has further delayed the reporting period for labs to submit their private-payer payment data to CMS for the second PAMA survey cycle. Labs are still required to collect their private payer payment data from the period Jan. 1, 2019 through June 30, 2019, but the reporting period has been delayed to the first quarter of 2022. Medicare CLFS rates will be frozen in 2021, and lab test codes will then be subject to 15% max annual cuts from 2022 through 2024. CMS plans to finalize these changes when it issues its Final MPFS Rule this fall.

8

#### Proposed Medicare Rate Changes for Key Pathology Codes for 2021

		Proposed	Actual	Proposed Rate
CPT/HCPCS	Short Description	2021	2020 <sup>2</sup>	% Change
88112-Global	Cytopathology, cell enhance technique	\$63.55	\$68.57	-7%
88112-26	Cytopathology, cell enhance technique	25.49	28.87	-12%
88112-TC	Cytopathology, cell enhance technique	38.07	39.70	-4%
88184-TC only	Flow cytometry/1st marker	66.78	68.21	-2%
88185-TC only	Flow cytometry/each add'I marker	21.94	22.38	-2%
88187-26 only	Flow cytometry, read 2-8	33.87	39.34	-14%
88188-26 only	Flow cytometry/read 9-15	58.71	66.04	-11%
88189-26 only	Flow cytometry, read 16 & greater	78.39	88.78	-12%
88305-Global	Tissue exam by pathologist	66.78	71.46	-7%
88305-26	Tissue exam by pathologist	34.52	39.34	-12%
88305-TC	Tissue exam by pathologist	32.26	32.12	0%
88307-Global	Level V, tissue exam by pathologist	271.96	281.50	-3%
88307-26	Level V, tissue exam by pathologist	76.13	86.62	-12%
88307-TC	Level V, tissue exam by pathologist	195.82	194.88	0%
88309-Global	Level VI, tissue exam by pathologist	412.93	427.66	-3%
88309-26	Level VI, tissue exam by pathologist	134.53	152.66	-12%
88309-TC	Level VI, tissue exam by pathologist	278.41	275.00	1%
88312-Global	Special stains, group 1	106.14	107.19	-1%
88312-26	Special stains, group 1	24.52	27.79	-12%
88312-TC	Special stains, group 1	81.62	79.40	3%
88313-Global	Special stains; group 2	77.1	77.23	0%
88313-26	Special stains; group 2	11.29	12.63	-11%
88313-TC	Special stains; group 2	65.81	64.6	2%
88331-Global	Pathology consult during surgery	92.27	100.33	-8%
88331-26	Pathology consult during surgery	57.42	65.32	-12%
88331-TC	Pathology consult during surgery	34.84	35.01	0%
88341-Global	Immunohistochemistry (Add'I stain)	88.07	94.19	-7%
88341-26	Immunohistochemistry (Add'I stain)	26.13	29.59	-12%
88341-TC	Immunohistochemistry (Add'I stain)	61.94	64.6	-4%
88342-Global	Immunohistochemistry (1st stain)	99.68	107.19	-7%
88342-26	Immunohistochemistry (1st stain)	32.26	36.81	-12%
88342-TC	Immunohistochemistry (1st stain)	67.42	70.37	-4%
G0416-Global	Prostate biopsy, any method	331.32	347.90	-5%
G0416-26	Prostate biopsy, any method	164.85	185.50	-11%
G0416-TC	Prostate biopsy, any method	166.46	162.40	3%
G0452-26	Molecular pathology interpretation	42.91	19.13	124%

<sup>1</sup>Payments based on the 2021 conversion factor of 32.26; <sup>2</sup>Payments based on the 2020 conversion factor of 36.09 Source: *Laboratory Economics* from CMS

### LabCorp Mid-Year 2020 Review

LabCorp (Burlington, NC) reported a net loss of \$86 million for the six months ended June 30, 2020, down from net income of \$376 million in the same period for 2019. Overall, LabCorp's reported half-year revenue was down by 1.4% to \$5.593 billion.

Looking specifically at LabCorp's lab testing business, revenue was down 2.5% to \$3.395 billion, including 1.4% gained from acquisitions. On July 28, the company held a conference call with analysts and investors to discuss its mid-year results. Here's a summary of some key topics discussed:

#### Volume Trends

Total volume (measured by requisitions) decreased by 12%, as organic volume declined by 13.4%, partially offset by acquisition volume of 1.4%. The decline in organic volume included a 21% reduction in base business (due to the pandemic), partially offset by Covid-19 testing of 7.6%. LabCorp reports that its base business improved to an approximate decline of 17% in the month of June versus a year ago, which was more than offset by Covid-19 testing, which contributed roughly 23% to total volume in June.

#### Pooled Covid-19 PCR Testing

As of the end of July, LabCorp was performing an average of roughly 125,000 Covid-19 PCR tests per day and had capacity to perform up to 180,000 tests per day. LabCorp says its average turn-around time for hospitalized patients was at 1-2 days, with 2-3 day TAT for other patients.

On July 24, LabCorp received FDA emergency use authorization (EUA) to perform pooled Covid-19 PCR testing on up to five patient samples at a time. A positive result would require each sample to be individually retested "I believe that the standard PCR testing in the fall will remain the most significant by far of the testing that we do for PCR. But, I do think that the pool testing will add to our capacity and give us additional capabilities," said LabCorp CEO Adam Schechter.

#### **Covid-19 Antibody Testing**

As of the end of July, LabCorp was performing an average of approximately 8,500 Covid-19 antibody tests per day and had capacity to perform up to 300,000 tests per day.

#### **New Acquisitions**

LabCorp acquired RDL Reference Laboratory (Los Angeles, CA) in mid-June. RDL was formed in 1977 by two UCLA-trained rheumatologists, Robert Morris, MD, and Allan Metzger, MD.

#### LabCorp Mid-Year Financial Summary (\$ millions)

Six months ended:	6/30/2020	6/30/2019	% Chg
Total revenue	\$5,592.6	\$5,672.9	-1.4%
LabCorp Diagnostics	3,394.7	3,482.9	-2.5%
Covance Drug Development	2,237.5	2,201.0	1.7%
Operating cash flow	574.5	419.3	37.0%
Capital expenditures	205.1	179.4	14.3%
Free cash flow	369.4	239.9	54.0%
Pretax income	29.3	524.7	-94.4%
Net income	-85.6	376.0	NA
Diluted EPS	-0.88	3.79	NA
Est'd number of requisitions	70.3	79.9	-12.0%
Est'd revenue per requisition	\$48.77	\$44.58	9.4%

Source: LabCorp and *Laboratory Economics'* estimates

RDL specializes in rheumatologic and autoimmune testing with the majority of its business coming from Southern California.

In July, LabCorp acquired the outreach testing business and entered into a comprehensive laboratory services contract with Franciscan Missionaries of Our Lady Health System (Baton Rouge, LA), one of the largest health systems serving Louisiana and Mississippi.

### Quest Diagnostics Mid-Year 2020 Review

Quest Diagnostics (Madison, NJ) reported net income of \$284 million for the six months ended June 30, 2020, down 27.2% from \$390 million in the same period for 2019. Overall, Quest's reported half-year revenue was down 5.1% to \$3.649 billion. Looking specifically at Quest's lab testing business: revenue was down 4.8% to \$3.508 billion, including 0.7% gained from acquisitions. Here's a summary of some key topics discussed during the company's July 23 conference call with analysts.

#### **Test Volume Trends**

Quest reported a 10.2% decline in its requisition volume for the first six months of 2020 versus the same period in 2019. Non-Covid-19 requisition volume fell by approximately 19%.

Quest CEO Steve Rusckowski said volumes were rebounding strongest at primary care offices, including Ob/Gyns, and also for anatomic pathology testing. He said that the weakest volume trends were in life insurance testing, pre-employment drug screening and wellness program testing for employers.

At the low end of its outlook, Quest is assuming an average 20% decline for its non-Covid-19 requisition volumes through the remainder of the year.

#### Covid-19 Testing

Quest has performed a total of roughly 8.5 million Covid-19 PCR-based tests year to date through June 30. Quest currently has the capacity to perform up to 130,000 Covid-19 PCR-based tests per day and plans to expand its capacity to 150,000 by early September.

Pooling patient samples for Covid-19 PCR-based tests will help expand capacity. Quest has begun combining four patient samples for pooled testing in locations where Covid-19 positivity rates are less than 5% (e.g., the Northeast). Quest has stated that it plans to bill for four tests when it performs pooled testing on four patient samples.

Meanwhile, Quest has performed a total of more than 2.5 million Covid-19 antibody tests year to date through June 30. Quest is currently performing about 20,000 antibody tests per day, well below its capacity for 200,000.

#### UnitedHealthcare's Preferred Lab Network

Rusckowski said that as a member of UnitedHealthcare's Preferred Lab Network, Quest had secured business from more than 180 out-of-network UHC labs.

#### Lab Acquisitions

"If anything, the pandemic could be an additional catalyst to help drive industry consolidation. Some transactions in the pipeline that were paused because of the pandemic are being revisited," said Rusckowski. Quest acquired Memorial Hermann Diagnostic Labs for \$120 million on April 6, and completed its purchase of 100% of the joint venture Mid America Clinical Labs in early August.

#### Quest Diagnostics Mid-Year Financial Summary (\$ millions)

6/30/2020	6/30/2019	% Chg
\$3,649	\$3,844	-5.1%
3,508	3,684	-4.8%
141	160	-11.9%
602	596	1.0%
165	132	25.0%
437	464	-5.8%
373	478	-22.0%
284	390	-27.2%
2.09	2.86	-26.9%
78.4	87.3	-10.2%
\$44.75	\$42.06	6.4%
	<ul> <li>6/30/2020</li> <li>\$3,649</li> <li>3,508</li> <li>141</li> <li>602</li> <li>165</li> <li>437</li> <li>373</li> <li>284</li> <li>2.09</li> <li>78.4</li> <li>\$44.75</li> </ul>	6/30/20206/30/2019\$3,649\$3,8443,5083,6841411606025961651324374643734782843902.092.8678.487.3\$44.75\$42.06

Source: Quest Diagnostics and Laboratory Economics' estimates

### Lab Stocks Up 42% Year To Date

Twenty one lab stocks have jumped by an unweighted average of 42% year to date through August 14. In comparison, the S&P 500 Index is up 4% so far this year. The top-performing lab stocks thus far in 2020 are Aspira Women's Health (formerly named Vermillion), up 289%; Opko Health, up 227%; and Biocept, up 210%. Shares of LabCorp and Quest Diagnostics are each up 12%.

Company (ticker)	Stock Price 8/14/20	Stock Price	2020 Price Change	Enterprise	Enterp Value/ Pevenue	Enterp Value/ EBITDA
LabCorp (LH)	\$189.84	\$169.17	12%	\$25,120	2.2	17.6
Quest Diagnostics (DGX)	120.01	106.79	12%	20,420	2.7	13.8
Sonic Healthcare (SHL.AX)*	34.03	28.75	18%	19,740	3.0	15.2
Exact Sciences (EXAS)	85.33	92.48	-8%	13,560	12.0	NA
Guardant Health (GH)	85.46	78.14	9%	7,990	31.0	NA
NeoGenomics (NEO)	38.93	29.25	33%	4,260	10.5	251.2
Natera (NTRA)	54.63	33.69	62%	4,210	12.3	NA
Invitae (NVTA)	30.02	16.13	86%	3,980	17.1	NA
Opko Health (OPK)	4.80	1.47	227%	3,970	4.1	NA
Veracyte (VCYT)	33.79	27.92	21%	1,810	16.1	NA
CareDx (CDNA)	32.46	21.57	50%	1,340	9.0	NA
Myriad Genetics (MYGN)	12.66	27.23	-54%	1,110	1.7	NA
Castle Biosciences (CSTL)	41.32	34.37	20%	653	10.4	59.7
Progenity (PROG)	7.71	15.00	-49%	465	4.1	NA
Aspira Women's Health (AWH)	3.15	0.81	289%	413	83.4	NA
DermTech Inc. (DMTK)	12.30	12.40	-1%	169	34.3	NA
Exagen (XGN)	16.48	25.40	-35%	148	3.8	NA
Biocept (BIOC)	0.90	0.29	210%	108	19.1	NA
Enzo Biochem (ENZ)	2.50	2.63	-5%	92	1.2	NA
Interpace Biosciences (IDXG)	5.78	5.00	16%	64	2.3	NA
Psychemedics (PMD)	5.18	9.15	-43%	28	0.8	6.2
Unweighted Averages			42%	\$109,650	13.4	60.6

\*Sonic Healthcare's figures are in Australian dollars

Source: Laboratory Economics from company reports and Capital IQ

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12



14





15



### Covid-19 Statistics for Select Countries (August 16, 2020)

	Population	Median	Urban	% <b>Р</b> ор	Total	Total	Deaths/
Country	(millions)	Age	<b>Pop %</b>	Obese	Cases	Deaths	1M Pop
Belgium	11.6	42	98%	22%	77,869	9,935	857
Peru	33.0	31	78%	20%	525,803	26,075	789
Spain	46.8	45	80%	24%	358,843	28,617	612
United Kingdom	67.9	40	83%	28%	317,379	41,361	609
Italy	60.5	47	69%	20%	253,438	35,392	585
Sweden	10.1	41	88%	21%	84,294	5,783	572
United States	331.2	38	83%	36%	5,531,282	172,630	521
Brazil	212.7	33	88%	22%	3,317,832	107,297	504
France	65.3	42	82%	22%	215,521	30,409	466
Mexico	129.1	29	84%	29%	517,714	56,543	438
Netherlands	17.1	43	92%	21%	63,002	6,172	360
Ireland	4.9	38	63%	25%	27,191	1,774	359
Canada	37.7	41	81%	29%	121,889	9,024	239
Iran	83.7	32	76%	26%	343,203	19,639	233
Switzerland	8.7	43	74%	20%	38,124	1,991	230
South Africa	59.3	28	67%	28%	583,653	11,677	197
Germany	83.8	46	76%	22%	224,562	9,290	111
Norway	5.4	40	83%	23%	9,965	261	110
Russia	145.9	40	74%	23%	922,853	15,685	107
Denmark	5.8	42	88%	20%	15,483	621	107
Austria	9.0	44	57%	20%	23,370	728	81
Israel	8.6	30	93%	26%	92,404	679	74
Turkey	84.5	32	76%	32%	248,117	5,955	71
Finland	5.5	43	86%	22%	7,731	333	60
Egypt	102.3	25	43%	32%	96,336	5,141	50
Bahamas	0.393	32	86%	32%	1,252	17	43
India	1,380.7	28	35%	4%	2,594,112	50,122	36
Iceland	0.342	38	94%	22%	2,011	10	29
Pakistan	220.9	23	35%	9%	288,717	6,168	28
Indonesia	273.5	30	56%	7%	139,549	6,150	22
Bangladesh	164.7	28	39%	4%	276,549	3,657	22
Australia	25.4	38	86%	29%	23,287	396	16
Japan	126.5	48	92%	4%	53,577	1,085	9
Hong Kong	7.5	45	100%	NA	4,481	69	9
South Korea	51.3	44	80%	5%	15,318	305	6
Nigeria	206.1	18	52%	9%	48,770	974	5
Ethiopia	115.0	19	21%	5%	28,894	509	4
China	1,439.3	38	61%	6%	84,827	4,634	3
Total Worldwide	7,794.8	31	56%	13%	21,642,864	769,492	99

Source: Worldometer and World Health Organization (August 16, 2020)