



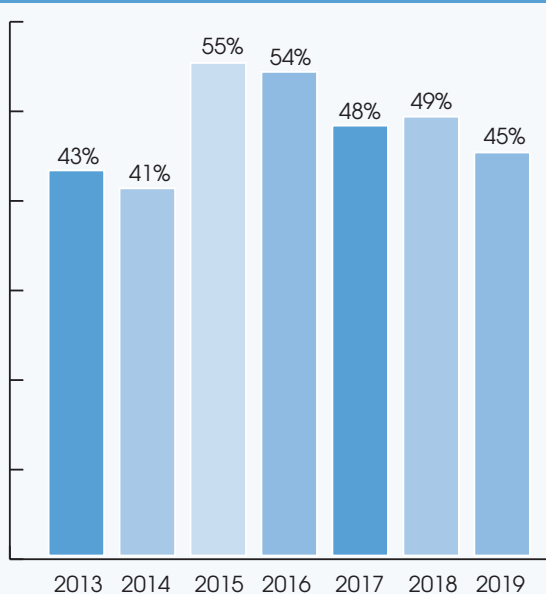
Revised Medicare Rates Soften Blow To Pathologists

The \$1.4 trillion omnibus legislative package passed by Congress on December 21 reduces budget neutrality cuts that would have slashed Medicare payment rates for pathology professional service by 9% in 2021 (see *LE*, December 2020). Overall Medicare payment cuts are now estimated to be approximately -2 to -3% for pathologists. For example, the professional interpretation rate for CPT 88305 will now be cut by 4% (rather than 12%) and the technical rate will increase by 5% (rather than a 5% cut). Congress mitigated the cuts to pathologists and other specialists by adding \$3 billion to the 2021 Medicare Physician Fee Schedule and by delaying the implementation of a new evaluation and management add-on code (G2211) for three years. See page 13 for an updated table with the newly revised 2021 rates for key pathology services.

Genetic Test Spending Booms Despite High Claims Denials

Forty-five percent of genetic test claims were denied by Medicare Part B contractors in 2019, according to an exclusive analysis of the latest available Part B carrier data by *Laboratory Economics*. The denial rate for genetic test claims has ranged from 41% to 55% since 2013, and it greatly exceeds the average 5% to 10% denial rate for routine lab tests. In spite of the high denial rates, Medicare Part B carrier spending on genetic tests increased by 51% per year between 2016 and 2019 (see *LE*, October 2020). For more on genetic test claims denials, see page 2.

Medicare Part B Claims Denial Rates for Genetic Tests



Source: Medicare Part B aggregate denied claims vs. submitted claims for CPT codes 81105-81599 and G0452, 0037U and 0047U for 2013-2019

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Genetic Test Spending Booms Despite High Claims Denials *(cont'd from page 1)*

Both Medicare Administrative Contractors (MACs) and commercial insurance plans are scrutinizing highly-reimbursed genetic test claims (\$500-3,500+) more carefully, according to Jeffrey Jones, Managing Partner at the consulting firm The Deerborne Group (Rancho Santa Fe, CA). He notes that the introduction of the McKesson Diagnostic Exchange program, or DEX Z-Code™ Identifier, in the 2012 timeframe, now administered by Palmetto GBA, has allowed payers to more transparently identify and evaluate tests to determine coverage policies so that they can be accurately tracked and reimbursed.

High-volume genetic tests with high Part B denial rates include CPT 81479 (unlisted molecular pathology procedure) at 76% denied claims, and CPT 81291 (MTHFR gene analysis) at 95% denial rate.

Meanwhile, several proprietary genetic tests, including Exact Sciences' Cologuard (CPT 81528), Myriad's Vectra DA rheumatoid arthritis test (CPT 81490) and CareDx's AlloMap heart transplant test (CPT 81595), have denial rates of less than 5%. Jones attributes these low denial rates primarily to the fact that these tests have gone through a rigorous evidence-based review process to evaluate their analytical and clinical validity as well as clinical utility studies to determine their medical necessity resulting in positive coverage determinations by both Medicare and private insurers.

Despite the overall high denial rates, Medicare Part B carrier payments for genetic tests soared to \$1.647 billion in 2019 from \$249 million in 2013--a six-year annual compound growth rate of 37%. Over the same time period, the number of Part B carrier allowed claims for genetic tests increased to 2.348 million, up 13% per year, and the average allowed payment per test increased to \$718, up 22% per year.

Medicare Part B Carrier Claims Denial Rates for Top 20 Genetic Tests

CPT	Short Description	2019 Submitted Claims	2019 Denied Claims	2019 Percent Denied
81528	Cologuard colorectal cancer screening	506,194	23,370	5%
81479	Unlisted molecular pathology procedure	463,783	354,284	76%
81406	Molecular pathology procedure, Level 7	203,257	50,924	25%
81404	Molecular pathology procedure, Level 5	195,300	147,960	76%
81408	Molecular pathology procedure, Level 9	179,012	33,152	19%
G0452	Molecular pathology interpretation	162,552	18,286	11%
81405	Molecular pathology procedure, Level 6	154,913	117,841	76%
81162	BRCA1, BRCA2 full seq analysis & full dup/del analysis	131,296	71,581	55%
81317	PMS2 full gene sequence analysis	106,140	25,370	24%
81401	Molecular pathology procedure, Level 2	106,081	34,349	32%
81291	MTHFR gene analysis	97,607	92,449	95%
81201	APC gene analysis, full sequence	94,456	32,601	35%
81225	CYP2C19 genotype	91,033	64,966	71%
81298	Hereditary colorectal cancer gene analysis	86,922	19,313	22%
81295	MSH2 gene analysis	86,403	19,022	22%
81241	Factor V gene analysis	85,491	77,183	90%
81226	CYP2D6 genotype	83,695	56,355	67%
81292	MLH1 gene analysis	80,530	65,099	81%
81240	Factor II gene analysis	80,487	72,713	90%
81321	PTEN full gene sequence analysis	79,466	61,214	77%
	Total for top 20 Part B genetic tests	3,074,618	1,438,032	47%
	Total for all Part B genetic tests	4,299,604	1,952,020	45%

Source: Medicare Part B national carrier data for CPT codes 81105-81599 and G0452, 0037U and 0047U for 2019

The Top 25 Genetic Testing Labs

Exact Sciences laboratory in Madison, Wisconsin is the nation's largest genetic testing lab, as measured by Medicare Part B carrier payments for 2018. The Exact lab, which exclusively performs Cologuard screening tests, received \$167 million of Medicare Part B payments in 2018.

The second largest is Genomic Health's lab in Redwood City, California, which received \$98 million in Part B payments in 2018—primarily for its Oncotype DX breast cancer test (CPT 81519). Genomic Health was acquired by Exact Sciences in November 2019.

Meanwhile, four of the genetic testing lab companies on the top 25 list have been charged with Medicare fraud under the U.S. Dept. of Justice's "Operation Double Helix" investigation (see *LE*, October 2019). These four labs, LabSolutions, Performance Laboratories, Acadian Diagnostic Labs and Clio Labs, received a combined total of \$147 million of Part B payments in 2018.

Top 25 Genetic Testing Labs by Medicare Part B Payments for 2018

Laboratory Name	City	Total Number of Tests	Total Medicare Payment Amount	Average Payment per Test
Exact Sciences	Madison, WI	334,425	\$166,697,647	\$498
Exact/Genomic Health	Redwood City, CA	27,852	98,343,876	3,531
LabSolutions LLC.	Atlanta, GA	269,619	77,439,034	287
Myriad Genetics	Salt Lake City, UT	29,756	51,049,253	1,716
CareDx	Brisbane, CA	13,332	39,012,032	2,926
Myriad/Assurex Health	Mason, OH	17,424	36,995,841	2,123
Personalized Genetics	Pittsburgh, PA	41,753	35,665,634	854
Invitae Corporation	San Francisco, CA	44,800	35,288,503	788
Foundation Medicine	Cambridge, MA	16,397	34,902,805	2,129
Myriad/Crescendo Bioscience	Salt Lake City, UT	41,767	34,353,641	823
Performance Laboratories	Oklahoma City, OK	38,247	32,481,172	849
Veracyte	So. San Fran, CA	34,741	25,969,902	748
Acadian Diagnostic Laboratories	Baton Rouge, LA	94,092	25,360,253	270
Suretox Laboratory	Elmwood Park, NJ	34,168	24,312,286	712
Ambry Genetics Corp.	Aliso Viejo, CA	38,054	23,131,720	608
Metric Lab Services	Ridgeland, MS	37,161	20,685,740	557
Med Health Services Management	Monroeville, PA	103,347	17,930,581	173
Trinity Clinical Laboratories	Lewisville, TX	22,629	15,938,303	704
Specialty Drug Testing	Monroe, LA	36,407	12,034,475	331
Castle Biosciences	Phoenix, AZ	2,858	11,603,050	4,060
Clio Laboratories	Lawrenceville, GA	32,018	11,398,057	356
Agendia Inc.	Irvine, CA	3,107	10,616,893	3,417
MDxHealth	Irvine, CA	5,033	9,955,293	1,978
Guardant Health	Redwood City, CA	2,835	9,439,245	3,330
CQuentia NGS, LLC.	Memphis, TN	27,504	9,321,512	339
Total for Top 25 Genetic Labs		1,349,326	\$869,926,747	\$645

Source: Medicare Provider Utilization and Payment Data for 2018

Spotlight Interview With Northwell's James Crawford

James Crawford, MD, PhD, oversees the integrated laboratory network for Northwell Health, which includes 23 hospital-based labs located throughout the New York City area and an 1,100-employee core lab based in Lake Success, NY. Here's an update from Dr. Crawford on how Northwell's labs are operating at this stage of the pandemic (see also *Laboratory Economics* April and May 2020 issues).



James Crawford,
MD, PhD

Can you describe the current state of Covid-19 testing at Northwell?

We are currently receiving about 10,000 to 12,000 patient specimens per day on weekdays and about 6,000 to 8,000 per day on the weekends. We aim to test the majority of these specimens inhouse. We send out several thousand specimens per day to various commercial labs—a key metric in our decision-making is their making daily capacity available to Northwell, and their turnaround time.

For inhouse testing, TAT is within single hours for our in-hospital “near-patient” testing, and 24-48 hours for test samples sent to our Core Lab (although we allow for a 72-hour TAT). For sendout testing, ideally the TAT is within 48 hours, but it does drift long on occasion, and we have to load-balance between outside commercial labs.

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

It remains a challenge. In particular, we started rapid PCR testing using Abbott's ID Now test at Northwell's urgent care clinics and selected hospital emergency departments in the summer. We have to carefully monitor the weekly Abbott supply versus weekly test consumption at the different system sites.

How does the pandemic situation in the New York City area today compare with last spring?

Last spring was a searing experience. At the height of the first wave in late March/early April, Northwell's hospitals had over 3,000 admitted Covid-19 patients for several weeks, and PCR test positivity rates that exceeded 70%. The uncertainty of whether or not we could manage through the crisis was excruciating. Fortunately, the peak subsided and both inpatient census and test positivity rates gradually decreased to low levels by mid-summer.

We used June through November to prepare for the second surge. Northwell's hospitals currently have about 1,200 admitted Covid-19 patients and an average PCR test positivity rate of 11% to 14%. This winter we've seen a slow, but steady, climb in cases. We're hoping that we'll be reaching a plateau soon. We feel prepared to make it through this sequence successfully.

Does Northwell perform Covid-19 antibody testing?

We started antibody testing in late April, beginning with a massive serosurvey of Northwell Health employees. From the beginning we have used multiple commercial platforms. Currently, Abbott Architect and Roche Cobas are our main platforms; we are also using Diasorin Liaison, Euroimmun, Ortho 3600 and Ansh Labs. We're performing an average of about 2,000 antibody tests per day. Seropositivity has risen from 18% to 20% during the summer to 25% to 27% currently.

Have non-Covid-19 test volumes fully rebounded?

In addition to Covid-19 patients, the Northwell system remains open for business for all other patients as well, and has been able to stay open during this second surge. So while the current surge in Covid-19 patients is less intense than Spring 2020, the laboratory work load has not diminished; it has increased. Our routine test volume is currently at approximately 95% of pre-pandemic levels. Including Covid-19 testing, our total Core Lab volumes are now running at 130% to 140% of pre-pandemic levels.

Is Northwell experiencing any shortages of lab employees?

Finding MLTs and MTs was a challenge even prior to the pandemic. We have maintained our workforce, but it has been a tiring journey through this pandemic. We are coping by having non-technical staff do as much support work as possible so that technical employees can work efficiently and maximize their time at the bench.

Where does the vaccination program at Northwell stand?

Northwell is distributing Covid-19 vaccines from BioNTech/Pfizer and Moderna. We're currently well into vaccinating people in Phase 1a (hospital workers, nursing home residents and staff, EMS workers, et al.). New York is now moving into Phase 1b (individuals age 65 and over, firefighters, police, teachers, et al.). I have received the first dose of the Moderna vaccine (without complications) and my second should occur on January 19.

Quest Signs Big Lab Services Deal With Hackensack Meridian Health

Quest Diagnostics will manage lab operations and perform testing for 11 Hackensack Meridian Health (HMH-Edison, NJ) hospitals under a long-term agreement. The deal represents Quest's largest professional laboratory services agreement to date. Financial terms were not disclosed.

Quest said non-time-sensitive testing from HMH medical centers will be moved to its Teterboro laboratory, as well as its new flagship lab in the ON3 complex in Clifton, New Jersey, which is opening later this year. The new 250,000-square-foot laboratory will be co-located with the Hackensack Meridian School of Medicine, also on the ON3 campus.

Separately, Hospital Cost Report data for HMH's hospitals show a combined annual laboratory department budget of \$162 million for 2019. Medicare Part B payments for nonpatient outreach testing totaled \$4.5 million, suggesting that HMH's overall nonpatient outreach business totals roughly \$20 million per year.

Enzo Shareholders Vote Against Re-Election Of Company's Chairman

Elazar Rabbani, PhD, Chairman and CEO of Enzo Biochem (New York City), did not receive a majority of the votes cast for re-election to another three-year term as Chairman at the company's annual shareholder meeting on January 4. Rabbani received 10.5 million votes in favor of his re-election and 13.4 million against it.

As a result, Rabbani has tendered his resignation to Enzo's board, which will decide whether to accept or reject his resignation, or whether other action should be taken. Rabbani will continue to serve as a director pending the board's decision.

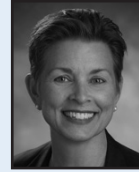
Rabbani, age 77, is a founder of Enzo and has served as the company's Chairman and CEO since its inception in 1976. He holds a 4.1% stake in the company.

The removal of Rabbani from Enzo's board might clear the way for a sale of the company's assets, including its Enzo Clinical Labs division. Enzo's largest shareholders, including Harbert Discovery Fund (11.7% stake) and Roumell Asset Management (5.8% stake) have been pushing the company to pursue a sale (see *LE*, December 2020).

Enzo Clinical Labs, which has current annual revenue of about \$80 million, is one of the largest commercial labs in the New York City area.

Spotlight Interview with ACL Laboratories' Barbara Bigler

ACL Laboratories performs more than 27 million tests per year for the Advocate Aurora Health Care System in Illinois and Wisconsin. *Laboratory Economics* recently spoke with ACL President Barbara Bigler.



Barbara Bigler

How many Covid-19 tests is ACL doing per day?

We are performing between 4,000 and 5,000 tests per day. We started in the middle of March with 500 a day. Our maximum capacity is about 8,000 tests per day. In the beginning we used some local reference labs, but for the most part, we are now doing Covid-19 testing ourselves.

Which analyzers do you use?

We have eight Hologic Panthers serving our two Central Labs. At our 28 hospital locations we have a mix of the Cepheid GeneExpert system and, soon to be, the Roche Liat. We use Quidel Sophia and the BD Veritor in ambulatory settings—both of these are rapid antigen tests. We also use Abbott's BinaxNow antigen test in our employee health department for testing.

What is your average turnaround time?

On the Panther, it's less than 24 hours. The others are rapid point-of-care tests.

Are you still having difficulty getting supplies?

We receive monthly reagent allocations; that said, we have needed to diversify platforms to meet the testing needs of our health care system.

Is ACL doing pooled sample Covid-19 testing?

Yes, we are pooling specimens on the Hologic Panther. We've improved our efficiency by adding an "Ask on Order" question to identify symptomatic patients. We do not pool if the sample is identified as coming from a symptomatic patient. It has been a very successful approach to expanding the number of tests offered while using fewer test kits and supplies. We are currently performing approximately three tests to one test kit by pooling specimens.

How many antibody tests do you do per day?

We run about 1,400 serology tests a week. We are meeting the current test demand and have the capacity to increase this testing methodology if requested. Overall positivity for antibody presence is 30%.

Have non-Covid-19 test volumes and revenues bounced back?

Yes, they have bounced back. We are meeting all our financial and performance targets for the second half of the year. We are seeing routine healthcare services and testing being provided beyond Covid-care, and that is helping the communities we serve.

Has the vaccine been made available to lab employees yet?

Yes. We would expect all laboratory persons who have been offered, and decided to have the vaccine shot, to have received the vaccine by the end of January or early February. We have 2,700 lab personnel. The healthcare system is in the process of defining the expanded vaccination plan for the patients and members of the community it serves.

Is antibody testing performed before vaccination or is everyone vaccinated?

Antibody testing is not formally ordered before a vaccine.

What are your projections for ACL in the coming year?

The overall focus for ACL Labs is addressing the strategic organizational needs for Advocate Aurora Health. The pandemic itself remains our top priority – managing the testing, the sup-

plies and the diversification of the platforms. Other than caring for our communities, we don't have a formal or extensive plan that takes us beyond managing the pandemic.

Do you anticipate volume and revenue growth in the coming year?

We are optimistic that we could have 1% to 2% overall growth but realize that with our current situation in this pandemic, expanded growth could be a difficult goal to reach.

What kind of long-term effect has the pandemic had on ACL?

The long-term effect is that we have learned a lot. An organization learns a lot during time of change, when things are unfamiliar. The need to be resilient and keep pace with the pandemic has required us to think about our work and the way in which we've established our standardized laboratory model. It has required us to be a little more diverse in our testing strategies. When supply is limited, it's hard to have just one kind of instrument, equipment or supply, and in response, we had to become nimbler and more flexible.

Rush Signs Clinical Trials/Lab Deal With LabCorp

Rush University System for Health (Rush-Chicago) has entered into a comprehensive agreement with LabCorp that covers clinical trials and lab services. Rush includes three hospitals, led by the flagship Rush University Medical Center (RUMC-697 beds), and has more than 1,800 affiliated physicians.

Robert DeCrease, MD, Director of Rush Medical Laboratories, says that initial interest on Rush's part was focused on LabCorp's drug development business, Covance. Rush will operate as a site partner, enrolling clinical trial participants, for Covance. This will give Rush patients access to new treatment options and Rush physicians will get first look at related research and studies, according to DeCrease.

DeCrease says that the laboratory service agreement includes four main components:

- 1) LabCorp has become the primary reference lab (replacing Quest Diagnostics) for Rush.
- 2) LabCorp will provide logistical and courier support to help expand Rush's lab outreach business. Some outreach tests may be sent to LabCorp facilities. Rush's lab outreach business may potentially be cobranded with LabCorp.
- 3) Rush will utilize LabCorp's experience with the Philips IntelliSite Pathology System as we begin to implement digital pathology.
- 4) Rush will utilize LabCorp supply chain management and purchasing expertise to help reduce costs.

DeCrease notes that the agreement does not involve inpatient testing or anatomic pathology services (other than digital pathology).

Separately, Hospital Cost Report data from Rush's three hospitals, RUMC, Rush Oakley and Rush Copley, show a combined annual laboratory department budget of \$120 million for the 12 months ended June 30, 2019. Medicare Part B payments for nonpatient outreach testing totaled \$2.3 million, suggesting that Rush's overall nonpatient outreach business totals roughly \$10 million per year.

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Spotlight Interview With Allina's Scott Leighty

Scott Leighty became Senior Vice President, Regional Hospitals and Clinical Services, at Allina Health (Minneapolis, MN) in June 2020. He was formerly with Atrium Health in North Carolina. Allina includes 12 hospitals, more than 90 clinics throughout Minnesota and western Wisconsin, and a 75,000-square-foot central lab on the campus of Abbott Northwestern Hospital. Minnesota was hit by a surge in Covid-19 cases between July and November. *Laboratory Economics* recently spoke with Leighty about how Allina's lab system was handling the Covid-19 pandemic.



Scott Leighty

Can you describe the current state of Covid-19 testing at Allina?

We are currently collecting about 10,000 patient specimens per week and test nearly all specimens in-house. We're using seven different platforms, but use the SeeGene Allplex 2019-nCoV PCR test for most volume at our central lab. In addition, we're primarily using the T2 Biosystems rapid test at our hospital labs.

We're also using rapid antigen testing at our emergency departments, but only when overall average positivity rates exceed 15%. Allina's Covid-19 positivity rates peaked in late November at 22% and currently average about 10%.

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

Test supply shortages were a major issue during the summer and fall when we were collecting as many as 16,000 Covid-19 specimens per week. During that surge, we were outsourcing as much as 80% of our Covid-19 specimens to commercial labs where turnaround times got as high as 5-7 days.

We got the SeeGene system online in early November and supplies have not been an issue. We now perform nearly all Covid-19 PCR testing inhouse. It's lowered our cost and turnaround times. We can provide test results within hours for patients under investigation and employees, and within 24 hours for all others.

Quick turnaround time has been especially important for minimizing unnecessary quarantines for Allina's nurses and other hospital workers, especially at our smaller hospitals.

Does Allina perform Covid-19 antibody testing?

We're using the Abbott antibody test, although demand is not high.

Have non-Covid-19 test volumes fully rebounded?

It's nearly back 100% to pre-pandemic levels.

What are your laboratory system goals for the new year?

Now that we have expanded our PCR testing capacity for Covid-19, we plan to expand our test menu for other viruses and infectious diseases as well. In addition, Allina is in the process of system-wide initiative to expand the services of Allina Health Cancer Institute at the Abbott Northwestern Hospital campus and many other sites. The central lab will be expanding its molecular cancer diagnostics staffing, equipment and test menu as part of that effort.

How have the PAMA rate reductions affected hospital lab outreach businesses?

PAMA has had a significant impact on hospital laboratories, many of which have sold or outsourced their outreach programs to national commercial laboratories. Large health systems that have highly efficient labs with strong foundations of technical support and smart supply contracting strategies are in a relatively good position to remain successful even under PAMA - particularly if their organizations are growing. However, long-term success will depend on the ability of these systems to eliminate redundant lab facilities and consolidate testing in fewer locations.

Spotlight Interview with TriCore Laboratories' Michael Crossey

TriCore Reference Laboratory (Albuquerque, NM) is the largest lab in New Mexico. *Laboratory Economics* recently spoke with its President and CEO Michael Crossey, MD, PhD.



Michael Crossey,
MD, PhD

How many Covid-19 tests is TriCore doing per day?

We have ranged from 1,000 to 5,000 tests per day, but 2,000 to 3,000 is average. Our max capacity is more than 10,000 per day, but we don't have the supplies to do that many. Overall, we are doing between 40% and 50% of the Covid-19 testing in New Mexico and have performed more than 700,000 tests to date.

What analyzers do you use? Are you still having difficulty getting supplies?

For Covid-19 PCR testing, we have two Abbott M2000s, two Roche 6800s, five DiaSorins, two Hologic Panthers and NeuMoDx at our core lab. At the hospitals we are using Cepheids, Roche Liats and Genmarks for rapid testing. Everything was in short supply at one point. Supplies seem better now although plastics for PCR (pipette tips, plates, etc.) can still be an issue at times.

What is your average turnaround time?

Currently we average under 24 hours, but the average was three to four days during our peak. We developed a multi-lane approach where symptomatic patients, pre-ops and healthcare workers were fast tracked. Test results for those in the fast track are usually turned around in less than 24 hours. The drive-through worried well are in the second tier.

How many antibody tests do you do per day?

About 50 to 100 per day. Our New Mexico Medical Advisory Team, which has two TriCore medical directors on it, couldn't find a significant medical utility for antibody testing.

Have non-Covid-19 test volumes bounced back?

Yes, for the most part, but 2020 overall was still under budgeted routine volume projections. Luckily, we had a fairly "V" shaped recovery in May and sustained recovery going forward. We are 5% under what we had projected for routine volumes, but we are above 2019 levels.

What impact has the pandemic had on TriCore lab revenues?

Certainly, we're below our budgeted projections for 2020. The loss of routine testing and the expenses of gearing up to cover Covid testing 24/7 was a financial expense. Between overtime and non-budgeted capital expenses, multiple vendors and premium reagent costs, we took on a lot. But our business office kept us afloat by getting bills out the door to the insurance companies, so we are still here.

Has the vaccine been made available to lab employees yet?

Yes, we started with our front line, patient-facing phlebotomists, then the lab folks handling samples, and now administrative support. New Mexico seems to be doing a great job getting these vaccines out. We expect to have all our employees vaccinated by the end of the month.

What are your projections for TriCore in the coming year in terms of Covid-19 testing?

I believe Covid-19 testing will level off and decline quickly. We have the combination Covid/Flu A/B up and running, although we have not seen much influenza this season.

What kind of long-term effect has the pandemic had on TriCore?

The digital transformation we all knew was coming is here, and it is not going anywhere. We will have more administrative folks who can, and want to, continue working from home permanently. Analytics is going to be its own product. Our population health reporting will continue and hopefully provide insight to insurance companies and health systems and add real value and improve care within the systems we serve. We need to better address the pandemic of chronic diseases that has been at our doorstep for decades, and data and population level insights are the only way to address those problems.

Spotlight Interview with IU Health's Clark Day

Indiana University Health (IU Health-Indianapolis) includes 18 hospitals and more than 1,500 physicians at more than 200 locations statewide. Laboratory Economics recently spoke with IU Health Laboratory System Services Vice President Clark Day.



Clark Day

How many Covid-19 tests is IU Health performing per day?

We have performed over 460,000 tests since our launch in mid-March 2020. In a typical week, we'll perform over 2,400 tests per day, but we are averaging just over 1,700 tests per day in recent weeks. This is down from a high of over 3,200 per day just before Thanksgiving. We're starting to see 4% to 5% increase in weekly test volumes as we start the New Year. The Roche cobas 8800 and cobas 6800 are our primary instruments.

What are your average turnaround times?

Our median turnaround time is 16 1/2 hours or less for internal IU Health patients and around 30 hours for the external reference lab customers we serve via our outreach business.

How many antibody tests do you do per day?

We launched antibody testing relatively early in the pandemic but there has been little up-take in orders for this test. We have performed just over 1,000 Covid-19 antibody tests so far. I think utilization of this test will increase considerably as the pandemic progresses and vaccinations are administered.

Is your health system using the rapid antigen Covid test?

We have the capability to perform rapid antigen testing in our regional hospital facilities and our central laboratory. We have limited testing to asymptomatic patients presenting to a hospital facility before admission to a double-occupancy room. We also make this testing available for IU Health team members who have incurred a high-risk exposure and to those serving in skilled nursing facilities.

Can you describe IU Health's core laboratory?

IU Health's core laboratory ("The Path Lab") is located at a separate and dedicated building in downtown Indianapolis and performs roughly 17 million billable tests per year. The Path Lab performs testing for IU Health's academic health center hospitals – Methodist Hospital, University Hospital and Riley Hospital for Children. The Path Lab also performs all microbiology, molecular and anatomic pathology testing for our statewide hospitals, as well as core clinical testing that they don't perform themselves.

Have non-Covid-19 test volumes bounced back?

Yes, we have largely recovered. Clinical chemistry testing had declined by about 30%, but has recovered and it appears the final impact will be on the order of negative 2% for 2020. Our microbiology testing experienced similar declines and we will close the year about negative 7% versus prior year. Anatomic pathology specimens had dropped by almost 75% but have returned to normal. However, the annual impact to AP was a 14% reduction from prior year.

Has the vaccine been made available to lab employees yet?

Yes. We are administering the vaccine in phases to all IU Health team members starting with frontline workers (including lab team members) followed by other licensed healthcare workers. All other team members will follow in early 2021. We expect most IU Health team members to receive a vaccine by early 2021.

What are your projections for IU Health's core laboratory in the coming year?

We expect to continue to perform Covid-19 testing throughout 2021 and beyond. As for other testing, we are working to expand our capabilities into NGS and molecular solid tumor testing. We expect an overall increase in our biopsies and resection cases as our specialty physician practices grow. We are also seeking to expand our testing through the addition of a toxicology department.

Spotlight Interview With Southeast Clinical Labs' CEO Steve Boyd

Steve Boyd and his wife Nicole Boyd started Southeast Clinical Laboratories (Birmingham, AL) in 2014. It's the third independent lab in Alabama that Steve has helped found. Previously, he helped start LabSouth (sold to Dynacare in 2000) and Southern Diagnostics (sold to Solstas Lab Partners in 2011). Southeast Clinical Labs (SCL) currently has 75 employees and performs roughly two million tests per year. *Laboratory Economics* recently spoke with Steve Boyd to discuss how SCL is navigating through the pandemic.



Steve Boyd

Does SCL perform Covid-19 PCR testing?

We started Covid-19 PCR testing in early May and are currently performing about 1,000 tests per day using three different platforms: ThermoFisher's QuantStudio 7, Becton Dickinson's BD Max and BioFire Defense. Our primary clients for Covid testing are physician offices and to a lesser extent nursing homes, schools and employers.

What are your turnaround times?

We provide same day results for Covid specimens we pick up in the morning and within 24 hours for all others.

How's the supply situation?

In the spring and summer, we had difficulty getting enough test reagents and specimen collection devices. We're now buying the raw materials and building our own collection devices. Lately, pipette tips have become hard to find.

Does your lab perform Covid-19 antibody testing?

Yes, we're using the Siemens Healthineers' spike antibody test. So far volumes have been weak, but demand is starting to pick up to confirm that vaccines are working.

Have your non-Covid test volumes rebound from the spring lows?

By July, our routine test volumes were back up to pre-pandemic levels, and with the addition of Covid-19 PCR testing, our overall total volume is significantly higher.

What are the advantages that a smaller independent lab has over the national labs?

Being local is a selling point with doctors and helps keep our turnaround times for all testing under 24 hours. But our biggest advantage is our flexibility and willingness to tailor services for physician office clients. Examples of our flexible service include the ability to: 1) modify test production times to meet a specific event or need; 2) customize test groupings to meet specific needs; and 3) answer phone calls with a live person that can answer over 95% of questions without transferring the call.

What are your biggest challenges?

Twenty or thirty years ago, the challenge was access to affordable information technology and the latest instrument systems. But the costs have come down and now everyone is pretty much competing on a level playing field in terms of technology. The biggest challenge today is access to commercial insurance contracts and networks. We currently do a lot of testing as an out-of-network provider, although we expect to continue to add more in-network contracts as we get bigger.

What are your goals for 2021?

Now that we've added several PCR testing platforms, we plan to add other non-Covid PCR tests to our menu. We're also adding toxicology testing and may expand our geographic service area to states outside of Alabama.

Lab Stocks Skyrocketed 84% In 2020 For Near Record-Breaking Year

Twenty-two lab stocks rose by an unweighted average of 84% in 2020—the best performance since 2000 when lab stocks jumped 155%. In comparison, the S&P 500 Index was up 16% (total return with dividends was 18%) in 2020. The top-performing lab stock in 2020 was Aspira Women's Health (formerly named Vermillion), which soared 728%. Aspira markets OVA1, a proprietary FDA-cleared blood test for identifying women with malignant ovarian tumor. Shares of LabCorp were up 20% in 2020, while Quest Diagnostics was up 12% (total return with dividends was 14%).

Company (ticker)	Stock Price 12/31/20	Stock Price 12/31/19	2020 Price Change	Enterprise Value (\$ mill)	Enterprise Value/Revenue	Enterprise Value/EBITDA
LabCorp (LH)	\$203.55	\$169.17	20%	\$25,840	2.1	12.4
Exact Sciences (EXAS)	132.49	92.48	43%	20,360	15.4	NA
Quest Diagnostics (DGX)	119.17	106.79	12%	19,600	2.3	10.0
Sonic Healthcare (SHL.AX)*	32.15	28.75	12%	19,340	2.9	13.6
Guardant Health (GH)	128.88	78.14	65%	11,920	43.9	NA
Natera (NTRA)	99.52	33.69	195%	7,960	22.0	NA
Invitae (NVTA)	41.81	16.13	159%	7,360	30.0	NA
NeoGenomics (NEO)	53.84	29.25	84%	6,090	14.3	309.0
CareDx (CDNA)	72.45	21.57	236%	3,370	19.9	NA
Veracyte (VCYT)	48.94	27.92	75%	2,900	25.7	NA
Opko Health (OPK)	3.95	1.47	169%	2,890	2.5	704.5
Myriad Genetics (MYGN)	19.77	27.23	-27%	1,520	2.5	NA
Castle Biosciences (CSTL)	67.15	34.37	95%	1,500	23.8	NA
Aspira Women's Hlth (AWH)	6.71	0.81	728%	682	151.2	NA
DermTech Inc. (DMTK)	32.44	12.40	162%	584	109.1	NA
Biodesix (BD SX)	20.16	18.00	-37%	583	21.8	NA
Progenity (PROG)	5.31	15.00	-65%	303	3.8	NA
Exagen (XGN)	13.20	25.40	-48%	132	3.4	NA
Enzo Biochem (ENZ)	2.52	2.63	-4%	107	1.3	NA
Biocept (BIOC)	4.44	2.90	53%	45	4.2	NA
Psychemedics (PMD)	5.09	9.15	-44%	32	1.3	NA
Interpace Biosciences (IDXG)	3.14	5.00	-37%	8	0.3	NA
Unweighted Averages			84%	\$133,126	22.9	209.9

*Sonic Healthcare's figures are in Australian dollars

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

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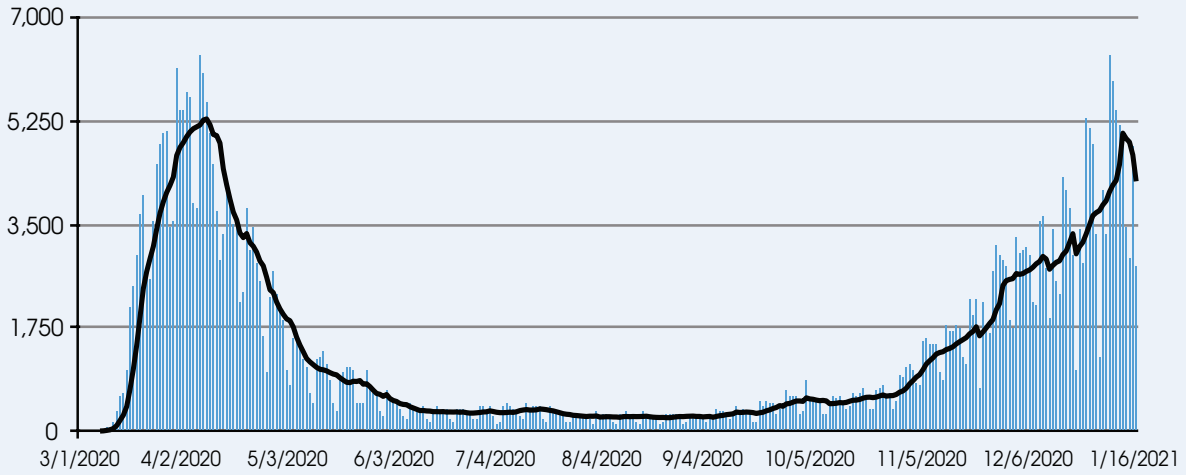
Updated Final Medicare Rate Changes for Key Pathology Codes for 2021

CPT/HCPCS	Short Description	Final 2021¹	Actual 2020²	% Rate Change
88112-Global	Cytopathology, cell enhance tech	\$67.69	\$68.57	-1%
88112-26	Cytopathology, cell enhance tech	27.91	28.87	-3%
88112-TC	Cytopathology, cell enhance tech	39.78	39.70	0%
88184-TC only	Flow cytometry/1st marker	69.79	68.21	2%
88185-TC only	Flow cytometry/each add'l marker	23.03	22.38	3%
88187-26 only	Flow cytometry, read 2-8	36.64	39.34	-7%
88188-26 only	Flow cytometry/read 9-15	62.81	66.04	-5%
88189-26 only	Flow cytometry, read 16 & greater	85.14	88.78	-4%
88305-Global	Tissue exam by pathologist	71.53	71.46	0%
88305-26	Tissue exam by pathologist	37.68	39.34	-4%
88305-TC	Tissue exam by pathologist	33.85	32.12	5%
88307-Global	Level V, tissue exam by pathologist	290.31	281.50	3%
88307-26	Level V, tissue exam by pathologist	83.39	86.62	-4%
88307-TC	Level V, tissue exam by pathologist	206.92	194.88	6%
88309-Global	Level VI, tissue exam by pathologist	441.75	427.66	3%
88309-26	Level VI, tissue exam by pathologist	146.90	152.66	-4%
88309-TC	Level VI, tissue exam by pathologist	294.85	275.00	7%
88312-Global	Special stains, group 1	113.05	107.19	5%
88312-26	Special stains, group 1	26.87	27.79	-3%
88312-TC	Special stains, group 1	86.19	79.40	9%
88313-Global	Special stains; group 2	81.65	77.23	6%
88313-26	Special stains; group 2	12.21	12.63	-3%
88313-TC	Special stains; group 2	69.44	64.60	7%
88331-Global	Pathology consult during surgery	104.68	100.33	4%
88331-26	Pathology consult during surgery	62.46	65.32	-4%
88331-TC	Pathology consult during surgery	42.22	35.01	21%
88341-Global	Immunohistochemistry (add'l stain)	93.86	94.19	0%
88341-26	Immunohistochemistry (add'l stain)	28.61	29.59	-3%
88341-TC	Immunohistochemistry (add'l stain)	65.25	64.60	1%
88342-Global	Immunohistochemistry (1st stain)	106.08	107.19	-1%
88342-26	Immunohistochemistry (1st stain)	35.24	36.81	-4%
88342-TC	Immunohistochemistry (1st stain)	70.83	70.37	1%
88377-Global	Morphometric analysis, ISH (quant or semi-quant)	424.65	411.78	3%
88377-26	Morphometric analysis, ISH (quant or semi-quant)	64.55	67.49	-4%
88377-TC	Morphometric analysis, ISH (quant or semi-quant)	360.10	344.29	5%
G0416-Global	Prostate biopsy, any method	354.16	347.90	2%
G0416-26	Prostate biopsy, any method	178.65	185.50	-4%
G0416-TC	Prostate biopsy, any method	175.51	162.40	8%
G0452-26	Molecular pathology interpretation	46.41	19.13	143%

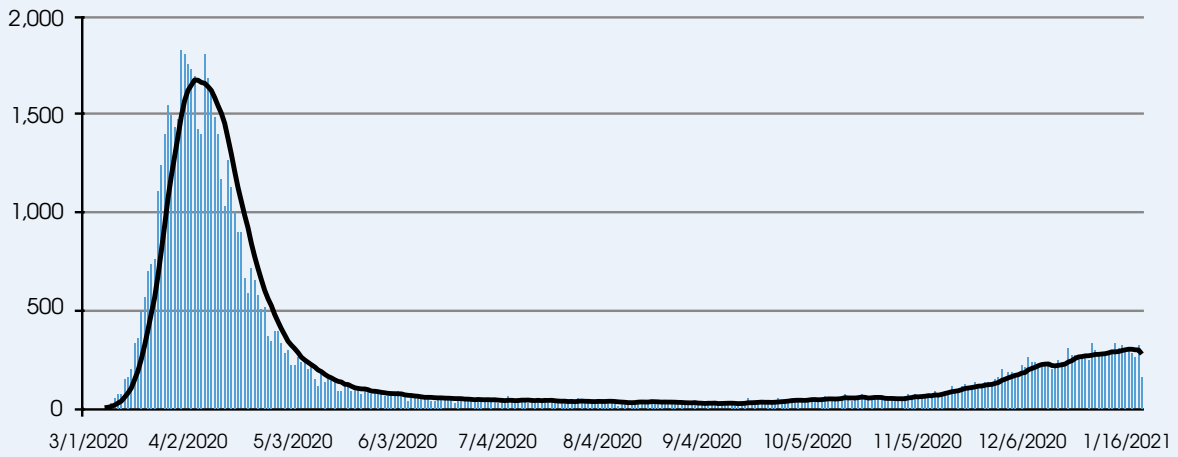
¹Payments based on the 2021 conversion factor of 34.89; ²Payments based on the 2020 conversion factor of 36.09

Source: *Laboratory Economics* from CMS

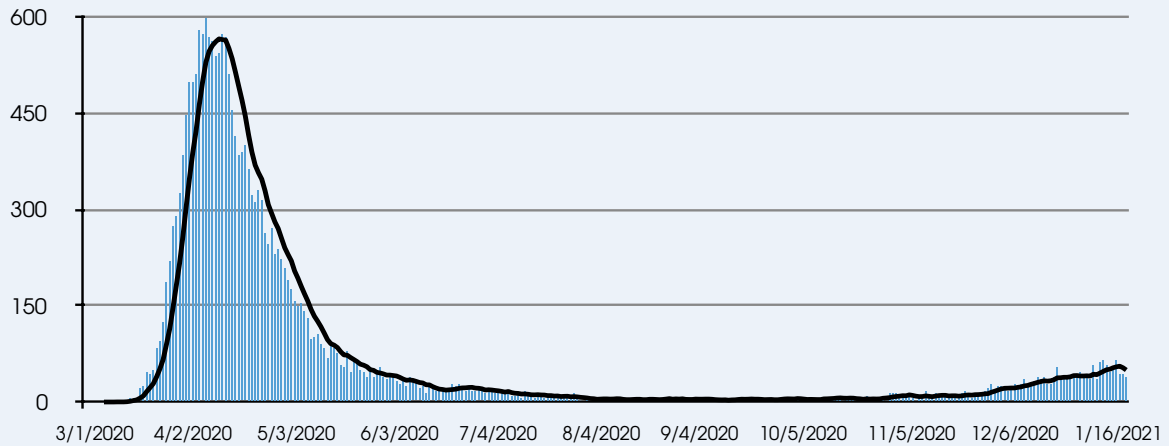
New York City Daily New Cases of Covid-19 with 7-Day Moving Avg. (March 5 through Jan. 16, 2021)



NYC Daily New Hospitalizations from Covid-19 with 7-Day Moving Avg. (March 5 through Jan. 16, 2021)

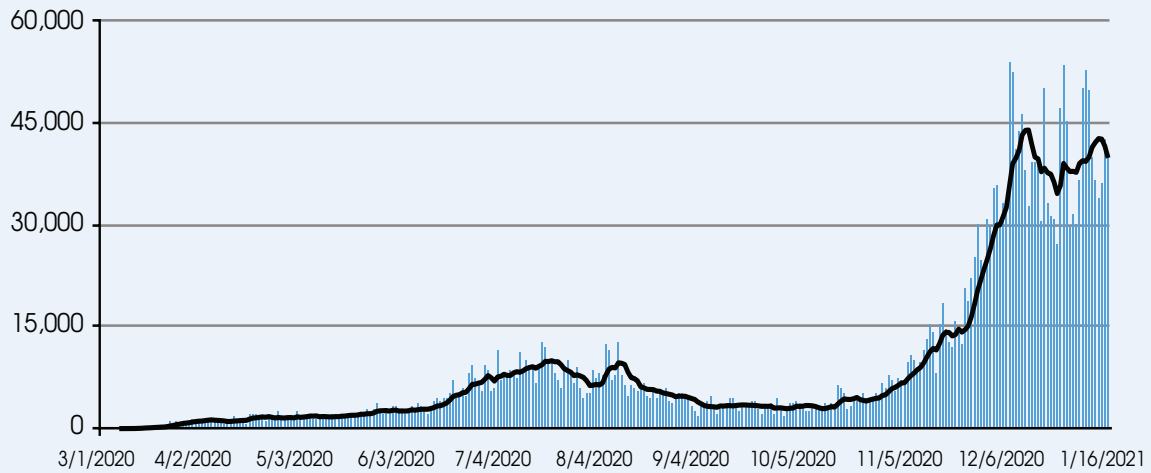


New York City Daily Deaths from Covid-19 with 7-Day Moving Avg. (March 5 through Jan. 16, 2021)

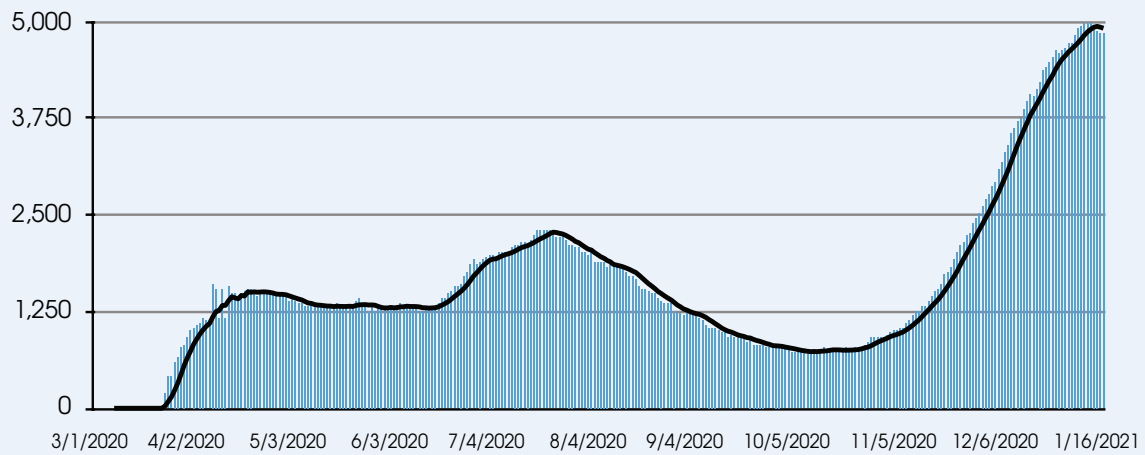


Source: NYC Department of Health and Mental Hygiene

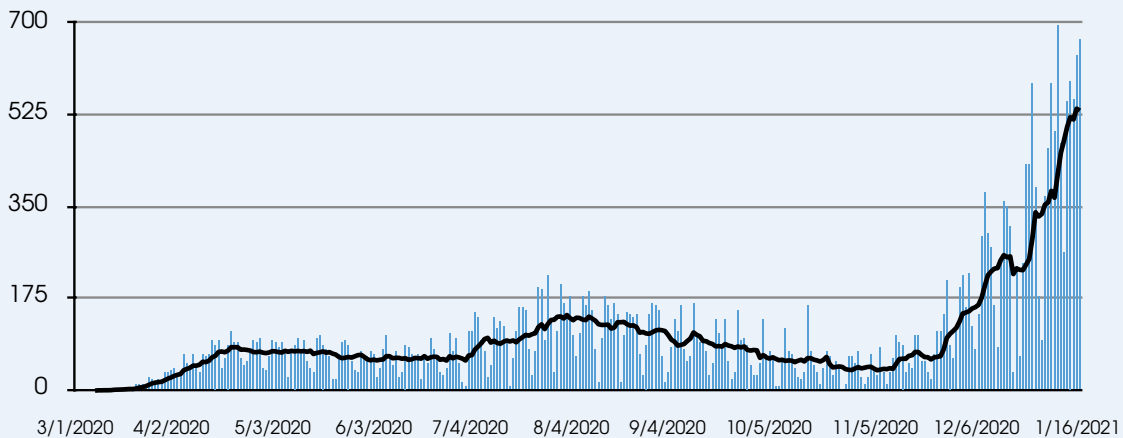
California Daily New Cases of Covid-19 with 7-Day Moving Avg. (March 5 through Jan. 16, 2021)



California ICU Patients with Covid-19 with 7-Day Moving Avg. (March 5 through Jan. 16, 2021)

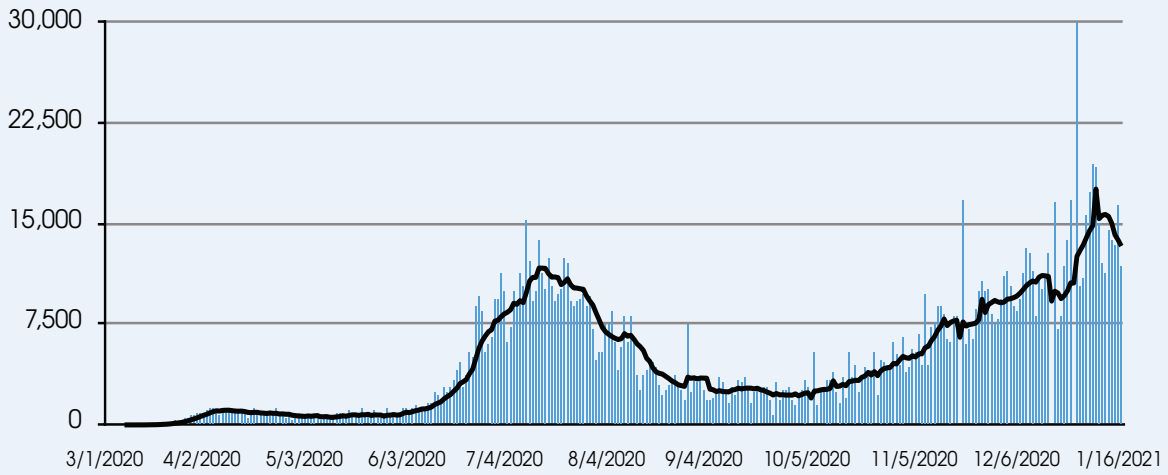


California Daily Deaths from Covid-19 with 7-Day Moving Avg. (March 5 through Jan. 16, 2021)

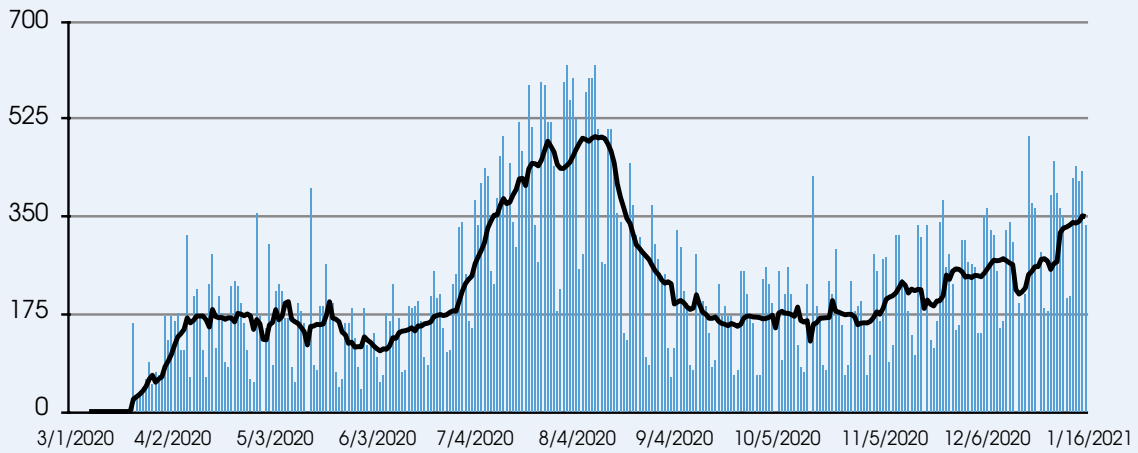


Source: The Covid Tracking Project

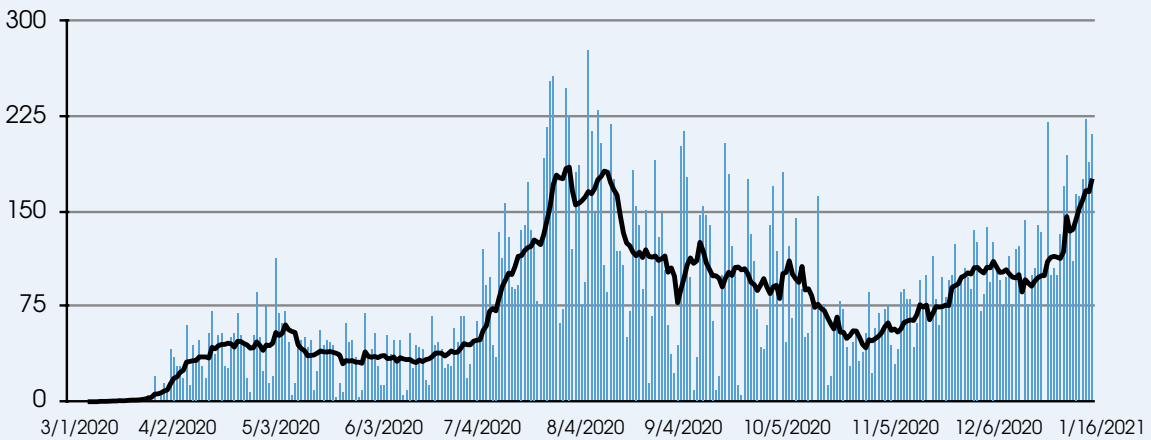
Florida Daily New Cases of Covid-19 with 7-Day Moving Avg. (March 1 through Jan. 16, 2021)



Florida Daily New Hospitalizations from Covid-19 with 7-Day Moving Avg. (March 1 through Jan. 16, 2021)



Florida Daily Deaths from Covid-19 with 7-Day Moving Avg. (March 1 through Jan. 16, 2021)



Source: The Covid Tracking Project