

LABORATORY

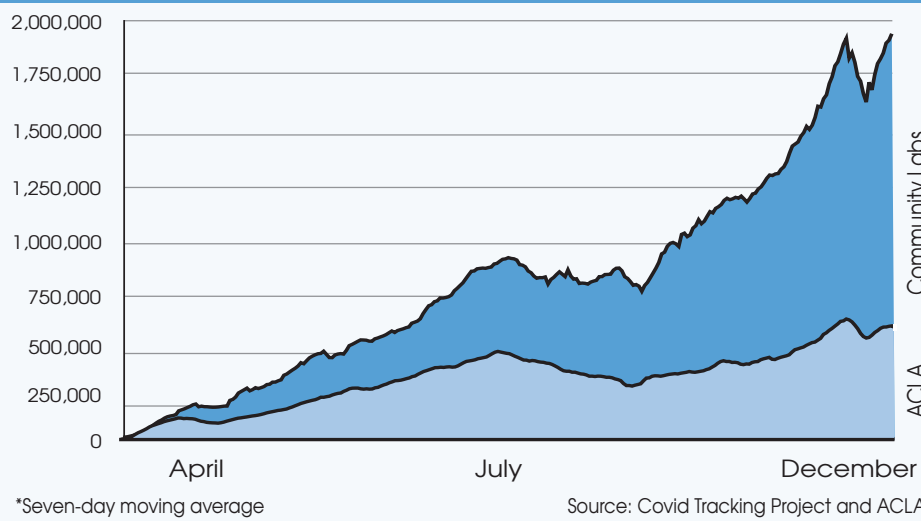
ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

Covid-19 PCR Test Volumes Hit 2 Million Per Day; Labs Worry About Payment And Potential Audits

The average daily volume of Covid-19 PCR testing performed in the United States is now averaging nearly two million tests per day, according to the Covid Tracking Project. Hospitals and independent labs are currently performing 73% of volume, while ACLA member labs account for 27%.

Daily U.S. Covid-19 PCR Test Volume* (March 16 to December 13, 2020)



The tremendous volume of Covid-19 testing, now equivalent to an annualized rate of 700+ million tests, is stressing the front-end capabilities of labs. Most private insurance payers have been uncharacteristically cooperative in paying Covid-19 test claims, but billing experts expect that to change once the pandemic ends.

Full details on pages 6-7.

Final 2021 Medicare Physician Fee Schedule Includes Big Rate Cuts To Pathology Services

The Final Medicare Physician Fee Schedule (MPFS) for 2021 reduces professional rates paid to pathologists by an average of 9%, while technical fees paid to pathology labs will fall by 5%. For example, the professional interpretation rate for CPT 88305 will decline by 12% to \$34.68. Meanwhile, primary care doctors, nurse practitioners and physician assistants, who rely on office and outpatient visits to evaluate and manage their patients, will see big rate increases from Medicare next year. The rate reductions for pathologists and other specialists, including anesthesiologists, radiologists and surgeons, are due to budget neutrality provisions in the Medicare Act that require payment hikes to be offset by equal reductions elsewhere. *Continued on page 2.*

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CMS Finalizes 2021 Physician Fee Schedule (*cont'd from page 1*)

Concern over potential shortages of primary care physicians is what led CMS to hike rates for the evaluation and management (E&M) codes used to reimburse these physicians for office/outpatient visits. Provider groups that will see the greatest increase in Medicare payments in 2021 include endocrinologists (+16%), rheumatologists (+15%), family practitioners (+13%), physician assistants (+8%) and nurse practitioners (+7%).

In addition to pathologists, other specialties scheduled for big Medicare rate cuts next year include radiologists (-10%), anesthesiologists (-8%) and general surgeons (-6%).

The College of American Pathologists and dozens of other physician organizations, including the American Medical Association, are urging Congressional leaders to advance a bill (H.R. 8702) that would halt the pending Medicare rate cuts scheduled to take effect on January 1, 2021. The bill would allow the significant pay increases to primary care providers to take effect, but would delay the scheduled rate cuts to pathologists and other specialties by freezing them at Medicare rates for 2020 for two years until 2023. The bill was introduced by Reps. Ami Bera, MD (D-CA) and Larry Bucshon, MD (R-IN) on October 30 and has gained support from more than 95 additional co-sponsors.

Meanwhile, barring legislative action, the following changes will become effective January 1, 2021:

Surgical Pathology

The global rate for CPT 88305 (Level IV, tissue exam) will drop by 7% to \$66.76 in 2021; professional interpretation down 12% to \$34.68; technical component flat at \$32.08.

The global rate for CPT 88307 (Level V, tissue exam) will decline by 3% to \$272.88; professional interpretation down 12% to \$76.48; technical up 1% to \$196.40.

The global rate for G0416 (Surgical pathology for prostate biopsy) is being reduced by 4% to \$332.84; professional down 11% to \$165.61; technical up 3% to \$167.23.

Immunohistochemistry

The global rate for CPT 88342 (IHC, first stain procedure) has been finalized to decrease by 7% to \$99.82; professional interpretation down 12% to \$32.41; technical down 4% to \$67.41.

The global rate for CPT 88341 (IHC, each additional stain) will decline by 7% to \$88.80; professional interpretation down 11% to \$26.25; technical down 3% to \$62.55.

Special Stains

The global rate for CPT 88312 (Special stains, group 1) will decline by 1% to \$106.62; professional interpretation down 11% to \$24.63; technical up 3% to \$81.99.

The global rate for CPT 88313 (Special stains, group 2) will be flat at \$77.46; professional interpretation down 10% to \$11.34; technical up 2% to \$66.11.

Flow Cytometry

The rate for the high-volume flow cytometry code 88185 (Flow cytometry/tech comp, each additional marker) will remain flat at \$22.36.

Molecular Pathology

CMS finalized a large increase in the work relative value units (RVUs) for Molecular Pathology Interpretation (HCPCS code G0452-26). The current rate of \$19.13 will more than double to \$43.10 in 2021.

Final Medicare Rate Changes for Key Pathology Codes for 2021

CPT/HCPCS	Short Description	Final 2021 ¹	Actual 2020 ²	% Rate Change
88112-Global	Cytopathology, cell enhance tech	\$63.52	\$68.57	-7%
88112-26	Cytopathology, cell enhance tech	25.60	28.87	-11%
88112-TC	Cytopathology, cell enhance tech	37.92	39.70	-4%
88184-TC only	Flow cytometry/1st marker	67.41	68.21	-1%
88185-TC only	Flow cytometry/each add'l marker	22.36	22.38	0%
88187-26 only	Flow cytometry, read 2-8	34.03	39.34	-13%
88188-26 only	Flow cytometry/read 9-15	58.98	66.04	-11%
88189-26 only	Flow cytometry, read 16 & greater	78.75	88.78	-11%
88305-Global	Tissue exam by pathologist	66.76	71.46	-7%
88305-26	Tissue exam by pathologist	34.68	39.34	-12%
88305-TC	Tissue exam by pathologist	32.08	32.12	0%
88307-Global	Level V, tissue exam by pathologist	272.88	281.50	-3%
88307-26	Level V, tissue exam by pathologist	76.48	86.62	-12%
88307-TC	Level V, tissue exam by pathologist	196.40	194.88	1%
88309-Global	Level VI, tissue exam by pathologist	414.5	427.66	-3%
88309-26	Level VI, tissue exam by pathologist	135.14	152.66	-11%
88309-TC	Level VI, tissue exam by pathologist	279.36	275.00	2%
88312-Global	Special stains, group 1	106.62	107.19	-1%
88312-26	Special stains, group 1	24.63	27.79	-11%
88312-TC	Special stains, group 1	81.99	79.40	3%
88313-Global	Special stains; group 2	77.46	77.23	0%
88313-26	Special stains; group 2	11.34	12.63	-10%
88313-TC	Special stains; group 2	66.11	64.60	2%
88331-Global	Pathology consult during surgery	97.87	100.33	-2%
88331-26	Pathology consult during surgery	57.69	65.32	-12%
88331-TC	Pathology consult during surgery	40.19	35.01	15%
88341-Global	Immunohistochemistry (add'l stain)	88.80	94.19	-7%
88341-26	Immunohistochemistry (add'l stain)	26.25	29.59	-11%
88341-TC	Immunohistochemistry (add'l stain)	62.55	64.60	-3%
88342-Global	Immunohistochemistry (1st stain)	99.82	107.19	-7%
88342-26	Immunohistochemistry (1st stain)	32.41	36.81	-12%
88342-TC	Immunohistochemistry (1st stain)	67.41	70.37	-4%
88377-Global	Morphometric analysis, ISH (quant or semi-quant)	404.13	411.78	-2%
88377-26	Morphometric analysis, ISH (quant or semi-quant)	59.63	67.49	-12%
88377-TC	Morphometric analysis, ISH (quant or semi-quant)	344.50	344.29	0%
G0416-Global	Prostate biopsy, any method	332.84	347.90	-4%
G0416-26	Prostate biopsy, any method	165.61	185.50	-11%
G0416-TC	Prostate biopsy, any method	167.23	162.40	3%
G0452-26	Molecular pathology interpretation	43.10	19.13	125%

¹Payments based on the 2021 conversion factor of 32.41; ²Payments based on the 2020 conversion factor of 36.09
Source: *Laboratory Economics* from CMS

CLFS: Review Of Data Reporting Period And Phase-In Of Payment Cuts

The final Medicare Physician Fee Schedule for 2021 included conforming changes to reflect the recent statutory revisions that affect the PAMA reporting schedule for labs and the resulting changes to the Medicare Clinical Laboratory Fee Schedule (CLFS).

There is nothing new here. However, a lot of changes have been made over the past year as a result of the FCAA/The LAB Act (enacted December 20, 2019) and the CARES Act (enacted March 27, 2020). Here's a quick review of the PAMA private-payer data survey and CLFS rate adjustment schedules.

Updated Medicare CLFS Outlook

CLFS Rates	Based on Lab Survey Period	Reduction Cap
2018	January 1, 2016 – June 30, 2016	-10%
2019	January 1, 2016 – June 30, 2016	-10%
2020	January 1, 2016 – June 30, 2016	-10%
2021	CLFS Rate Freeze	0%
2022	January 1, 2016 – June 30, 2016	-15%
2023	January 1, 2019 – June 30, 2019	-15%
2024	January 1, 2019 – June 30, 2019	-15%
2025	January 1, 2019 – June 30, 2019	unlimited

Source: CMS

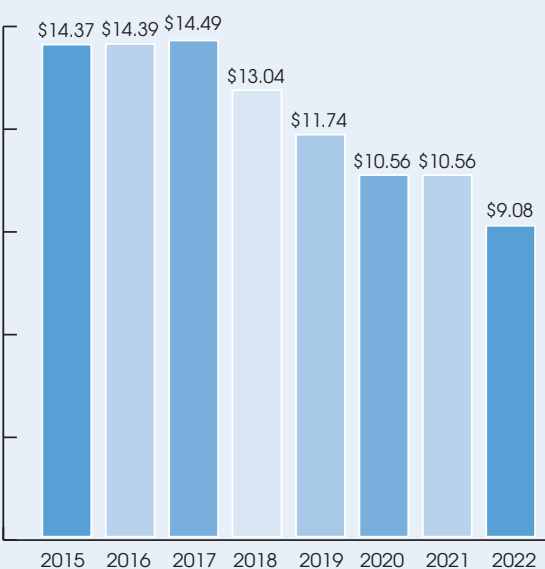
Medicare CLFS Rates

Medicare CLFS rates for 2021 will be unchanged from 2020. However, in 2022, CLFS rates will be subject to any remaining cuts left over from the initial PAMA private-payer survey—this will lead to cuts of roughly 10-15% for most high-volume routine clinical lab test codes in 2022. CLFS rate adjustments resulting from the second PAMA private-payer survey will go into effect starting in 2023.

PAMA Private-Payer Data Reporting Schedule

The new reporting schedule calls for applicable labs to report their private-payer payment data (collected from January 1 to June 30, 2019) to CMS in the first quarter of 2022. In addition to independent labs and POLs, nearly every hospital lab that performs outreach tests on nonpatients is now also required to report.

CLFS Rate History for the Comprehensive Metabolic Panel



Source: Medicare CLFS, 2015-2021 and projected rate for 2022

Example of Medicare Rate Changes for Comprehensive Metabolic Panel

The comprehensive metabolic panel (CPT 80053) is the most frequently billed clinical lab test. Medicare CLFS reimbursement for CPT 80053 had been stable until PAMA rate reductions of 10% per year kicked in from 2018 to 2020. The CLFS rate will be frozen at \$10.56 in 2021, followed by a reduction of 14% to \$9.08 in 2022, which represents the last portion of adjustment needed to meet the median rate determined by the initial PAMA private-payer data survey. The rate for CPT 80053 and other CLFS tests in 2023-2025 will be determined by the second PAMA private-payer data survey.

Spotlight Interview with Sonic Healthcare USA's Jerry Hussong

Sonic Healthcare USA (Austin, TX) became the nation's third largest laboratory company after acquiring Aurora Diagnostics for \$540 million in January 2019. In September, Sonic Healthcare USA was awarded a grant of \$20.8 million from the National Institutes of Health under its Rapid Acceleration of Diagnostics (RADx)* initiative to expand Covid-19 testing capacity. *Laboratory Economics* recently spoke with Jerry Hussong, MD, Chief Executive Officer at Sonic Healthcare USA, about Sonic's role in Covid-19 testing in the United States.



Jerry Hussong, MD

How many Covid-19 tests is Sonic currently performing in the United States?

We are currently performing approximately 40,000 Covid-19 PCR tests per day, with the capacity to do more than 100,000.

Testing is done at 12 of our laboratory locations on instrument systems from Abbott, Hologic, Roche, and Thermo Fisher. Our highest-volume laboratories include Clinical Pathology Laboratories (Austin, TX), Sunrise Medical Laboratories (Hicksville, NY) American Esoteric Laboratories (Memphis, TN), WestPac Labs (Santa Fe Springs, CA) and Clinical Labs of Hawaii (Honolulu, HI).

Is Sonic experiencing any shortage of test supplies, reagents or sample collection swabs?

Supply chains were stretched in the spring as labs began to ramp up volume and demand surged, but the supply situation has improved. A bigger issue has become workforce shortages, especially medical technologists and pre-analytical staff.

Is Sonic using pooled testing?

We're doing pooled testing of 3-5 specimens in select localities, especially where the average positivity rate is less than 5%.

How are Sonic's turnaround times for Covid-19 testing?

Greater than 90% of our specimens are reported within 48 hours of receipt in the laboratory. We're operating 24 hours/7 days per week. Having multiple instrument platforms in our laboratories spread out geographically helps and we continue to work to lower our turnaround times even further.

Describe Sonic's antibody testing for Covid-19.

We're using Abbott's IgG antibody test and Roche's total antibody test. Demand has so far been low, but is likely to increase as Covid-19 vaccines roll out.

Can you give an update on your integration of Aurora Diagnostics?

Aurora Diagnostics has become the foundation of Sonic Healthcare USA's Anatomic Pathology Division. With this acquisition, we now have 330 pathologists including numerous subspecialists. Integration activities include the transition of employee benefits and IT services. Like all laboratories, our anatomic pathology test volumes declined in March and April but have since rebounded and are now approaching pre-pandemic levels. I'm optimistic that next year, as the pandemic subsides, people that missed screenings and postponed procedures will return to actively managing their healthcare.

When do you see the Covid-19 pandemic ending?

With FDA approval of effective vaccines imminent, everyone in the United States should have the opportunity to be vaccinated by the late spring or early summer. The key is for the general population to trust and understand the importance of getting vaccinated.

*This project is supported by the NIH Rapid Acceleration of Diagnostics (RADx) program and has been funded in whole or in part with federal funds from the National Institutes of Health Office of the Director, Department of Health and Human Services, under Contract No. 75N92020C00027.

Labs Worry About Covid-19 Test Payment And Potential Audits *(cont'd from p. 1)*

Challenges on the Front End

The tremendous volume of Covid-19 PCR testing combined with the emergency use of non-traditional specimen collection sites have made it more difficult to obtain complete and accurate test orders, notes John Donnelly, President and CEO of FrontRunnerHC (Plymouth, MA), which provides automated software systems that verify and fix patient insurance and demographic information on lab test orders. For example, Donnelly says that nurses, phlebotomists and volunteers at drive-through locations at hospitals, stadiums and malls are often understaffed and under extreme pressure to speed the patient registration and sample collection process, leading to missing patient information and errors on test orders. Regular non-Covid-19 clinical lab test orders are estimated to have first-time submission rejection rates that average roughly 9% for eligibility, while rejection rates for Covid-19 test orders can be over four times higher, according to Donnelly. Determining insurance eligibility is especially important because it's a necessary first step before labs can bill a patient's insurance plan or the HRSA Covid-19 Uninsured Program, he adds.



John Donnelly

Private Payer Rates for Covid-19 PCR Tests

Most private insurance plans are reimbursing labs in a range of \$70 to \$100 per Covid-19 PCR test (U0003/U0004), according to Kwami Edwards, Chief Customer Officer at TELCOR Inc. (Lincoln, NE). He says the average rate paid is approximately \$82. Many private insurers have matched Medicare's \$100 rate, while some are paying below. In particular, Edwards notes that UHC-managed Medicare and Medicaid plans are towards the lower end of the reimbursement range.



Kwami Edwards

Covid-19 Antibody Testing

Edwards says that private insurers are paying an average of roughly \$50 per Covid-19 antibody test claims, including claims with more than one antibody tested. The bigger problem is the high denial rate—averaging 25% for Covid-19 antibody test claims. Private payers are rejecting antibody tests as “a non-covered charge” (denial code PR96) or “service not covered” (C0294) and placing the payment burden on patients. This may change as Covid-19 vaccines are rolled out and antibody testing is performed to confirm effectiveness, notes Edwards.

Billing the HRSA Uninsured Program

The U.S. Department of Health and Human Services, through the Health Resources and Services Administration (HRSA), launched a Covid-19 Uninsured Program Portal, allowing labs that have performed Covid-19 testing for uninsured individuals to submit claims for reimbursement effective February 4, 2020 at reimbursement rates equivalent to Medicare rates. The HRSA program covers specimen collection, diagnostic and antibody testing, accounts for approximately 12% of all third-party payer Covid-19 claims volume and has been running fairly smoothly, according to Lale White, Executive Chairman and CEO of XIFIN Inc. (San Diego, CA).

Medicare's New Two-Day Turnaround Add-On Payment

As an incentive to improve turnaround times, effective January 1, 2021, CMS is lowering payment for high-throughput Covid-19 PCR tests (U0003/U0004) from \$100 to \$75, but adding an add-on payment code (U0005) if the test result is reported within two calendar days of specimen pickup. To qualify for the \$25 add-on payment, labs will also need to complete the majority (51%) of their high-throughput Covid-19 PCR tests in two calendar days or less for all of their patients (not just their Medicare patients) in the previous month.

White notes that the new add-on payment code will increase billing complexity, require LIS system changes (e.g., keying correct date of specimen pickup vs. date of service). The two-calendar-day limit will be especially difficult to meet for hospitals, nursing homes and labs that bill Medicare for Covid-19 tests that they send to an outside reference lab.



Lale White

White says that most private insurance plans have not yet decided whether or not they will follow Medicare and use the U0005 code in 2021. UnitedHealthcare seems to be leaning toward requiring labs to use the U0005 code. Other private insurers are leaning toward simply lowering their reimbursement rate for U0003/U0004 to somewhere between \$75 and \$100 in 2021, but not adding the complexity of the new U0005 code, notes White.

Direct Self-Paying Patients

“Our data is indicating that direct patient bill is about 1-2% of volume and that it is billed between \$100 and \$115 and usually collected up front in advance of performing the test,” according to XIFIN’s White.

The Potential for Audits and Clawbacks

The Pandemic is costing the commercial health insurance industry trillions of dollars, notes Ann Lambrix, Vice President at Vachette Practice Management (Sylvania, OH). Right now, private insurers are paying lab test claims for Covid-19 PCR tests and are not over-scrutinizing medical necessity. It would be bad PR to do otherwise, she notes. However, at some point in 2021 or 2022, Lambrix expects private insurers and Medicare contractors to begin auditing labs and demanding clawback payments for tests they deem to have been medically unnecessary.



Ann Lambrix

A similar situation has occurred over the past year, as UnitedHealthcare has gone back to review payments made to pathology labs that billed prostate biopsies using CPT 88305 as early as 2017, rather than the lower-paying G0416. Some labs were forced to pay back hundreds of thousands of dollars, notes Lambrix.

Lambrix expects that private insurers will especially scrutinize tests added on to Covid-19 test claims, including add-on testing for strep, pneumonia, flu, and respiratory virus panels. “Private insurers may seek clawback payments unless there was a negative Covid-19 test that made it medically necessary for additional testing.”

Another potentially problematic area is testing for people suspected to have had exposure to someone with Covid-19. The ICD-10 codes (Z20.828 and Z20.822) associated with ordering suspected-exposure testing may be likely to trigger audits by private insurers to prove these codes were correctly applied, says Lambrix.

So what should labs be doing to support the medical necessity of the Covid-19 tests and add-on tests they perform? “This is difficult for Covid as the nature of the testing and the waivers due to Public Health Emergency bend the rules a bit. Basically, I would recommend keeping documentation supporting the medical need for testing for at least the next five years. This could be in the form of a physician order, patient charts/notes, or documentation supporting that an outbreak occurred in a facility. This goes for both suspected-exposure and add-on testing,” answers Lambrix.

Finally, Lambrix advises labs that are billing a high volume of Covid-19 tests through the HRSA Uninsured Portal to make sure they are documenting their process for determining if a patient is truly uninsured. While the portal will kick back claims for patients with commercial insurance, it does not automatically do this for those with Medicare or Medicaid.

“If you don’t believe there will be audits, you haven’t been in this business long enough,” she adds.

Spotlight Interview with NorDx CEO Stan Schofield

NorDx (Scarborough, ME), the largest regional laboratory in Maine, serves 12 community hospitals that are a part of MaineHealth, along with more than 600 physician office, nursing home and other clients. *Laboratory Economics* recently spoke with CEO Stan Schofield about how the lab is handling the Covid-19 pandemic.



Stan Schofield

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

We are averaging 3,000 per day. We developed a lab-developed test in February and launched it in March. We had enough reagents for 2,000 patients, but we didn't think we would have that need. It became clear quickly that the numbers would go up. Toward the end of March, we began having problems getting supplies. All our standing orders for reagents were being diverted to other laboratories.

In March we only tested critical patients and health care workers. We couldn't test non-symptomatic people. At that time, we were testing 300 to 400 people per day. In the last week of April, we started pooled testing for asymptomatic patients. We still do individual tests for symptomatic individuals. Our turnaround is 12 to 16 hours although for emergency department patients we can do six hours.

We were using Roche equipment and supplies, but they stopped sending master media and extraction kits, so in May we made a decision to pivot and we changed brands. We bought Thermofisher's KingFisher, and we have pieced things together. We have three liquid handling robots, three KingFisher extraction units and six Thermocyclers that we use for Covid testing. I also have Roche equipment (Cobas 4800) that we are not using for Covid testing – we are running routine tests on that. We are running our own Covid test because we can't get kits.

Have you been able to meet demand for testing?

Our demand is 4,500 to 5,000 tests per day, and we are doing about 3,000 a day. I have the technology and the machines, but I don't have the people. The bottleneck is on the pre-analytic end. We are still having problems getting supplies. Sometimes things don't show up when we expect them because they have been redirected. It's like a constant scavenger hunt. Every day is a little scary. I am absolutely disappointed in what has happened with supplies. We were promised a lot of supplies that we have not received.

Which lab do you use for excess demand for Covid testing?

We do not send out work. No big lab has an acceptable turnaround time. Currently we can perform 4,000 tests per day. We have purchased additional equipment and are training more staff so that we can increase to 5,000 tests per day.

What is the current positivity rate for Covid testing at NorDx?

Our positivity rate for symptomatic patients is currently 9%. Asymptomatic is about 1-2% depending on the source of specimen (colleges, nursing homes, et al.). Positivity rates for all specimens are trending up rapidly. Initially we were pooling 4:1 for asymptomatic cases, but with the recent surge we've lowered that to 2:1.

Are you offering antibody testing?

Yes, we offer it, but there is almost no demand for it. We have done about 700 since June. It doesn't prove anything. I think quantified antibody testing will be key going forward.

Are you doing antigen testing?

No. We are evaluating it. Antigen testing only works if a patient is “hot.” If the viral load is low, antigen testing won’t work. It works great if you’re symptomatic, but not if you are asymptomatic. We are considering antigen testing for acute respiratory care patients in a community setting. We are evaluating several brands, but it also depends on what we can get.

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

We are at 92% of where we were a year ago, across the board.

Are you experiencing any shortages in staffing?

Absolutely. We have an aging workforce. My information technology and finance people work from home. Phlebotomy is really critical. We have a phlebotomy school that we are running every day of the week, but we can’t keep up with the demand. We could also use more molecular techs. We are currently retraining med techs to turn them into molecular techs.

How big a hit is the pandemic having on NorDX’s revenues?

In the spring revenues dropped, but they’ve come back up since then. In August and September, we surpassed last year’s total revenue. Our average revenue-per-requisition is way up – over \$90 – because of Covid-19 testing.

How has the influenza season been so far? Lower than normal?

We have had no confirmed flus with molecular. Last year we used Roche Liat to test for flu, but now we are only getting 200 test kits per week for 12 hospitals. We have not launched a combo test yet because there has not been a need. I think the flu season will be modest because the Covid protocols should reduce spread of the flu virus also.

Quest Signs Two Hospital Lab Deals; Completes MACL Purchase

Quest Diagnostics will provide laboratory management services for Montefiore Nyack Hospital and its renal physician practice Highland Medical Rockland Renal Associates in Rockland County, New York. Services Quest will provide include day-to-day management of hospital labs, lab supply chain management and esoteric reference testing. Montefiore Nyack Hospital has 251 beds and an annual lab department budget of \$20 million, according to its Hospital Cost Report for 2019.

In addition, Quest announced a new agreement with Goshen Hospital (Goshen, IN) to provide supply chain management expertise in addition to the reference testing which Quest currently provides. Goshen Hospital has 107 beds and an annual lab department budget of \$8 million, according to its Hospital Cost Report for 2019.

Separately, Quest reported that it completed its acquisition of Mid America Clinical Laboratories (MACL-Indianapolis, IN) effective August 1 (see *LE*, July 2020). Quest paid \$118 million in cash to acquire the remaining 56% of the joint venture that it did not already own from Ascension St. Vincent (25%), Community Health Network (22%) and AmeriPath/CoLab (9%). The out-of-pocket expense to Quest was \$93 million after adjusting for the \$18 million it got back from its AmeriPath/Colab stake. The purchase price valued MACL at \$198 million, or approximately 1.6 times its annual revenue of roughly \$125 million. MACL, with approximately 800 employees, had been the largest independent lab in Indiana.

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Battle Continues Between Enzo And Harbert Discovery Fund

Alabama-based investment management firm Harbert Discovery Fund continues to feud with Elazar Rabbani, PhD, Chairman and CEO of Enzo Biochem (New York City) over the future of the clinical lab and diagnostic products company.

Harbert is an activist investor fund that targets small-cap companies that it believes are undervalued. Harbert accumulated shares in Enzo from May to August 2019 at prices ranging from \$3.07 to \$3.65 per share. It currently owns 5.6 million shares, or an 11.7% stake, making it Enzo's largest shareholder.

In February 2020, Harbert nominated and won Enzo board seats for two directors, Fabian Blank and Peter Clemens (see *LE*, March 2020). However, Clemens and Blank both resigned from Enzo's board in November. "It appears that Chairman and CEO Rabbani has created such an extremely hostile environment that Pete and Fabian found their position untenable as minority members in opposition to Mr. Rabbani's continued mismanagement," according to a letter Harbert sent to Enzo's board of directors on November 18. Harbert called for the resignation of Rabbani, followed by an immediate pursuit of the sale of the company. Harbert believes Enzo could be sold at a minimum of 2x its current annualized revenue, or \$5.51 per share.

Dr. 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. His board seat is up for reelection to another three-year term this January.

In response to Harbert's letter, Enzo filed a lawsuit against Harbert on November 27 in the Southern District of New York. Enzo alleges that Harbert has made material misrepresentations to Enzo's shareholders and that its board nominees, Clemens and Blank, were unprepared and never proposed a single strategic plan to help Enzo. Enzo says that Harbert is seeking to "force a fire sale" to the detriment of shareholders. Enzo alleges that Harbert has made false or misleading statements in violation of Securities Exchange Act rules. Enzo is seeking a permanent injunction to stop Harbert from making future misrepresentations, correct past alleged false statements, and pay monetary damages to cover Enzo's related proxy contest expenses and attorneys' fees.

Enzo's Revenue Jumps Driven by Covid-19 Testing

Separately, Enzo reported net income of \$299,000 for the three months ended October 31, 2020 versus a net loss of \$7.6 million for the same period a year ago; total revenue increased by 42% to \$28.7 million.

Enzo's Clinical Lab Division recorded a 66% revenue increase to \$21.2 million. The improvement was driven by Covid-19 testing. Total volume grew to 300,000 accessions in the latest three-month period versus approximately 200,000 a year earlier. Average revenue per accession increased to more than \$69 per accession versus \$62 in the previous year's period.

Enzo Got \$7 Million PPP Loan

The CARES Act expanded the U.S. Small Business Administration's (SBA) business loan program to create the Paycheck Protection Program (PPP), which provides employers with loans for the purpose of retaining employees and maintaining salaries. PPP loans are wholly or partially forgivable if spent on payroll and certain other operating expenses. Enzo, which has 408 full-time and 40 part-time employees, was one of four publicly-traded lab companies that received a PPP loan. Enzo received a PPP loan of \$7 million in April, while Interpace Biosciences received \$3.5 million, Psychemedics got \$2.2 million and Aspira Women's Health (formerly named Vermillion) got \$1 million.

Quest Survey Reveals Majority Of Americans Have Skipped Or Delayed Care

A survey sponsored by Quest Diagnostics shows that 60% of U.S. adults have skipped or delayed some in-person medical treatments or appointments during the Pandemic. About one in five Americans (22%) have skipped or delayed blood work or lab testing specifically. Among those skipping or delaying care, 53% said they were scared of exposure to the virus. The nationally representative survey was conducted online by The Harris Poll on behalf of Quest Diagnostics and collected responses from 2,050 U.S. adults between November 10-12.

Harvey Kaufman, MD, Senior Medical Director at Quest Diagnostics, says that Americans' reluctance to maintain routine or preventative medical visits due to the Pandemic could lead to a surge in non-Covid-19 health conditions once the Pandemic abates or a vaccine is widely distributed.

Kaufman says that conditions that progress more quickly and with higher severity pose the greatest risks. Some of his top concerns include:

1. Cancer: Some cancers progress faster than others and have worse outcomes, such as lung cancer. A study of Quest's testing data published in *JAMA Network* showed that the rate of cancer diagnoses across six common cancer types (ie, breast, colorectal, lung, pancreatic, gastric, and esophageal) decreased by 46% between March 1 and April 18, 2020. In addition, more recent data show that there are fewer women being newly identified with breast cancer and men with prostate cancer.

2. Infectious diseases: Quest has identified major gaps in testing and expected diagnosis of hepatitis C and of chlamydia and gonorrhea. These infections are treatable/curable, but undiagnosed patients can have progressive disease and spread infections to others.

3. Chronic conditions: Top of the list may be patients with atrial fibrillation who are taking Coumadin that should be monitored every four weeks/once monthly. Being outside the therapeutic range increases risk of stroke and hemorrhage.

Monitoring diabetes may be less of an issue but deferring testing for too long will likely lead to more patients exhibiting poor/inappropriate control and long-term damage to different organs/functions. An analysis of Quest's testing trends published in *Population Health Management* showed that the rate of diabetes (hemoglobin A1C) testing declined by as much as 66% during approximately the first two months of the Pandemic, compared with the previous year.

4. Pediatric lead testing: Identifying exposure early can lead to remediation or removal of the child from a toxic environment. Identification of one child in a household can often lead to protection of other children, including those not yet conceived. Some schools eliminated lead testing requirements this year. This remains a public health crisis that is a high priority.

5. Routine health screenings: Early identification of risks and medical conditions sometimes identifies more advanced disease. Many conditions, like high blood pressure and high cholesterol, are silent in the early stages. Although deferral may be appropriate for a short time, at some point, more advanced disease that will affect our bodies will mean more aggressive treatment and poorer outcomes.

Quest's non-Covid testing volumes have rebounded since the lows in March and April. However, as of late September, these volumes were still down roughly 5% to 10% compared with last year. "With a vaccine not likely to reach the general public until spring at the earliest, the healthcare community needs to do a better job of helping Americans get back to routine care now. Early diagnosis can save lives and putting off preventative care and chronic disease treatment could make the difference between life and death," notes Kaufman.

Lab Stocks Have Vaulted 70% Year To Date

Twenty two lab stocks have risen by an unweighted average of 70% year to date through December 11. In comparison, the S&P 500 Index is up 13% so far this year. The top-performing lab stocks thus far in 2020 are Aspira Women's Health (formerly named Vermillion), up 474%; Invitae, is up 251%; and CareDx is up 220%. Shares of LabCorp are up 21%, while Quest Diagnostics is up 14%.

Company (ticker)	Stock Price 12/11/20	Stock Price 12/31/19	2020 Price Change	Enterprise Value (\$ mill)	Enterprise Value/Revenue	Enterprise Value/EBITDA
LabCorp (LH)	\$204.16	\$169.17	21%	\$25,420	2.0	12.1
Quest Diagnostics (DGX)	122.06	106.79	14%	19,990	2.4	10.2
Exact Sciences (EXAS)	129.50	92.48	40%	19,910	15.1	NA
Sonic Healthcare (SHL.AX)*	32.72	28.75	14%	19,020	2.8	13.4
Guardant Health (GH)	124.09	78.14	59%	11,440	42.2	NA
Invitae (NVTA)	56.60	16.13	251%	9,260	37.7	NA
Natera (NTRA)	96.56	33.69	187%	7,710	21.3	NA
NeoGenomics (NEO)	50.75	29.25	74%	5,400	12.7	274.1
Opko Health (OPK)	4.45	1.47	203%	3,220	2.8	786.2
CareDx (CDNA)	68.94	21.57	220%	3,150	18.6	NA
Veracyte (VCYT)	55.54	27.92	99%	2,880	25.6	NA
Myriad Genetics (MYGN)	19.72	27.23	-28%	1,530	2.6	NA
Castle Biosciences (CSTL)	59.74	34.37	74%	995	15.8	NA
Aspira Women's Hlth (AWH)	4.65	0.81	474%	468	103.6	NA
Biodesix (BDSX)	15.74	18.00	-37%	421	19.5	NA
Progenity (PROG)	4.73	15.00	-68%	230	2.9	NA
DermTech Inc. (DMTK)	11.49	12.40	-7%	174	32.4	NA
Exagen (XGN)	13.22	25.40	-48%	144	3.7	NA
Enzo Biochem (ENZ)	2.55	2.63	-3%	103	1.4	NA
Biocept (BIOC)	5.41	2.90	87%	53	5.0	NA
Psychemedics (PMD)	4.87	9.15	-47%	36	1.4	NA
Interpace Biosciences (IDXG)	3.40	5.00	-32%	7	0.3	NA
Unweighted Averages			70%	\$131,562	16.9	219.2

*Sonic Healthcare's figures are in Australian dollars

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

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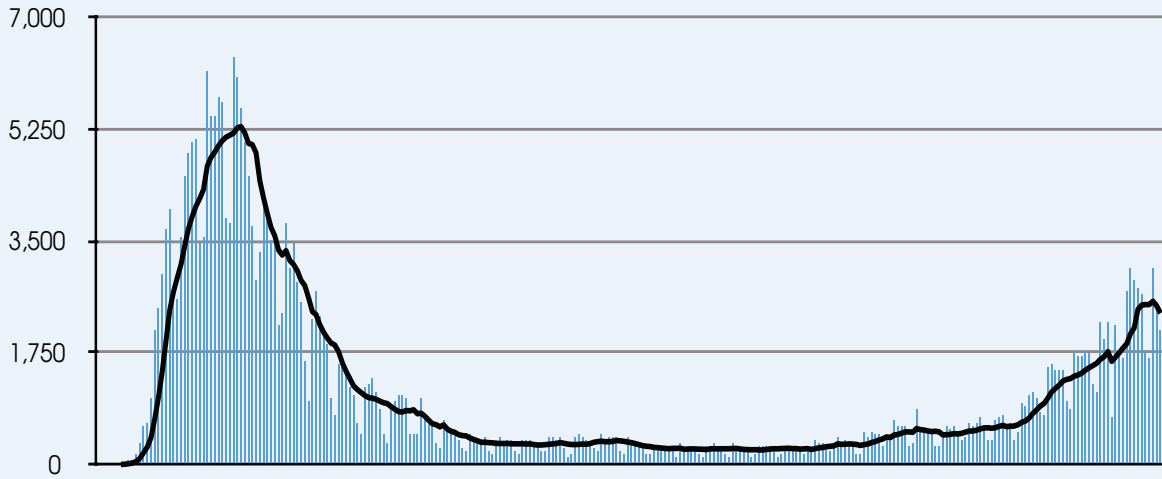
Covid-19 Statistics for 70 Countries (December 13, 2020)

Country	Population (millions)	Median Age	% Urban Population	% Pop Obese	Total Cases	Total Deaths	Deaths/1M Pop
Belgium	11.6	42	98%	22%	605,966	17,902	1,542
Peru	33.2	31	78%	20%	983,045	36,609	1,103
Italy	60.4	47	71%	20%	1,825,775	64,036	1,060
Spain	46.8	45	80%	24%	1,741,439	47,624	1,018
Bosnia and Herzegovina	3.3	43	52%	18%	100,306	3,298	1,008
North Macedonia	2.1	39	59%	22%	73,025	2,096	1,006
Slovenia	2.1	45	55%	20%	96,311	2,063	992
United Kingdom	68.0	40	83%	28%	1,830,956	64,026	941
United States	331.9	38	82%	42%	16,549,366	305,082	919
Argentina	45.4	32	92%	28%	1,494,602	40,668	896
Czech Republic	10.7	43	74%	26%	579,079	9,535	890
France	65.3	42	82%	22%	2,365,319	57,761	884
Mexico	129.1	29	84%	29%	1,241,436	113,704	878
Brazil	213.2	33	88%	22%	6,880,595	181,143	849
Armenia	3.0	35	63%	20%	148,325	2,486	838
Chile	19.2	34	88%	28%	569,781	15,846	826
Bulgaria	6.9	45	76%	25%	178,952	5,626	812
Ecuador	17.7	28	64%	20%	201,524	13,874	781
Bolivia	11.7	26	69%	20%	147,030	9,014	768
Panama	4.3	30	68%	23%	190,585	3,331	767
Columbia	51.0	31	81%	21%	1,417,072	38,866	760
Sweden	10.1	41	88%	21%	320,098	7,514	742
Hungary	9.7	43	72%	26%	280,400	6,965	722
Romania	19.2	43	55%	23%	556,335	13,385	698
Switzerland	8.7	43	74%	20%	373,831	5,976	688
Iran	84.5	32	76%	26%	1,108,269	52,196	618
Poland	37.8	40	60%	23%	1,135,676	22,864	604
Netherlands	17.2	43	92%	21%	603,603	10,019	584
Austria	9.0	44	57%	20%	322,463	4,473	495
Ireland	5.0	38	63%	25%	75,756	2,123	428
Bahamas	0.395	32	86%	32%	7,659	163	413
South Africa	59.6	28	67%	28%	852,965	23,106	387
Canada	37.9	41	81%	29%	454,852	13,350	352
Ukraine	43.6	41	69%	24%	894,215	15,154	347
Greece	10.4	45	85%	25%	123,842	3,540	340
Israel	9.2	30	93%	26%	356,250	2,990	325
Russia	146.0	40	74%	23%	2,653,928	46,941	322
Germany	83.9	46	76%	22%	1,320,592	22,171	264
Guatemala	18.1	23	52%	21%	129,099	4,405	244
Kuwait	4.3	37	100%	38%	146,218	911	212
Turkey	84.7	32	76%	32%	1,809,809	16,199	191
Morocco	37.1	30	64%	26%	397,597	6,589	178
Saudi Arabia	35.0	32	84%	35%	359,749	6,036	172
Denmark	5.8	42	88%	20%	107,116	935	161

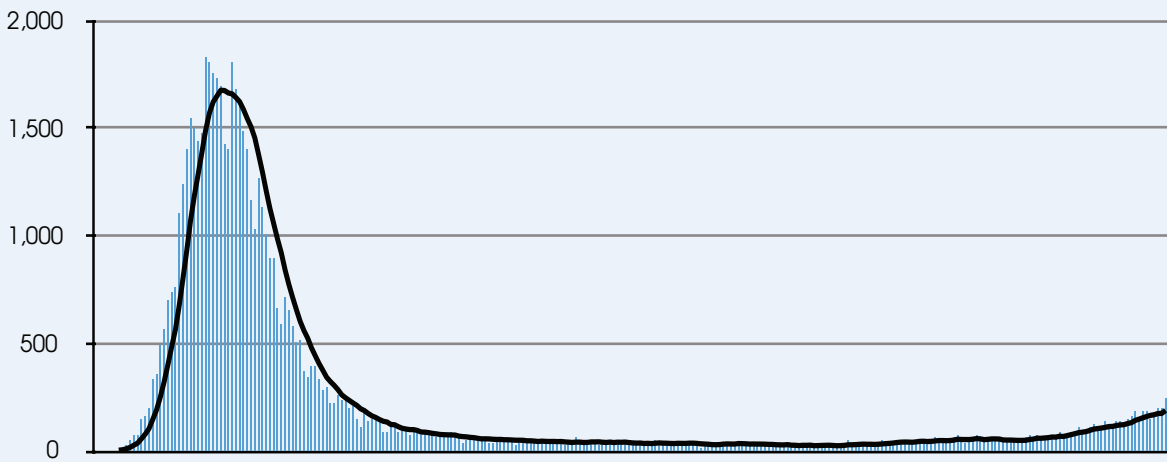
Country	Population (millions)	Median Age	% Urban Population	% Pop Obese	Total Cases	Total Deaths	Deaths/ 1M Pop
India	1,386.1	28	35%	4%	9,859,615	143,065	103
Jamaica	3.0	31	55%	25%	11,608	271	91
Finland	5.5	43	86%	22%	30,810	453	82
Iceland	0.342	38	94%	22%	5,557	28	82
Philippines	110.2	26	47%	6%	449,400	8,733	79
Norway	5.4	40	83%	23%	40,803	387	71
Indonesia	274.8	30	56%	7%	617,820	18,819	68
Egypt	103.2	25	43%	32%	121,089	6,898	67
Nepal	29.4	25	21%	4%	248,423	1,698	58
Bangladesh	165.4	28	39%	4%	490,533	7,052	43
Pakistan	222.8	23	35%	9%	438,425	8,796	39
Australia	25.6	38	86%	29%	28,030	908	35
Sudan	44.3	20	35%	7%	21,147	1,344	30
Kenya	54.3	20	28%	7%	91,526	1,586	29
Yemen	30.1	20	38%	17%	2,083	606	20
Japan	126.3	48	92%	4%	174,299	2,534	20
Ethiopia	116.2	19	21%	5%	116,297	1,803	16
Malaysia	32.6	30	78%	16%	83,475	415	13
South Korea	51.3	44	80%	5%	42,766	580	11
Nigeria	208.4	18	52%	9%	72,757	1,194	6
Ivory Coast	26.7	19	51%	10%	21,639	133	5
New Zealand	5.0	38	87%	31%	2,096	25	5
Singapore	5.9	42	99%	6%	58,320	29	5
China	1,439.3	38	61%	6%	86,725	4,634	3
Thailand	69.9	40	51%	10%	4,209	60	1
Vietnam	97.7	33	37%	2%	1,397	35	0.4
Avg. for High Median Age Countries (>35)	2,794.9	42	76%	22%	35,937,359	767,494	518
Avg. for Low Median Age Countries (<35)	3,758.3	27	60%	18%	30,794,301	767,187	328
Avg. for High Obesity Countries (>20%)	2,058.5	37	76%	25%	53,750,498	1,328,267	569
Avg. for Low Obesity Countries (<20%)	4,494.7	30	50%	8%	12,981,162	206,414	78
Avg. for High Urban Pop Countries (>80%)	1,337.0	39	87%	24%	37,558,600	933,024	486
Avg. for Low Urban Pop Countries (<80%)	5,216.3	33	57%	18%	29,173,060	601,657	393
Total for 70 Countries	6,553.2	35	69%	20%	66,731,660	1,534,681	429
Total Worldwide- All Countries	7,831.8	31	56%	13%	72,220,080	1,613,863	207

Source: World Health Organization and Worldometer (December 13, 2020)

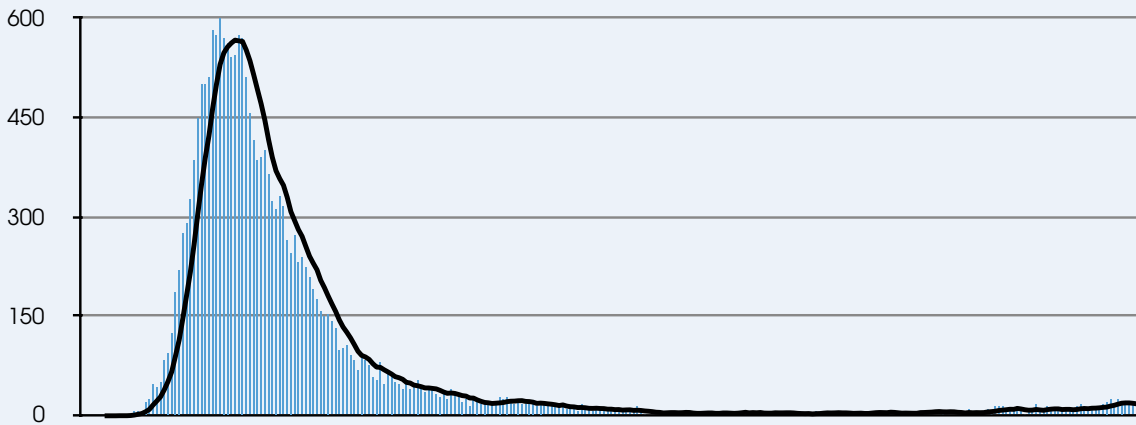
New York City Daily New Cases of Covid-19 with 7-Day Moving Avg. (March 1 through Dec. 9, 2020)



NYC Daily New Hospitalizations from Covid-19 with 7-Day Moving Avg. (March 1 through Dec. 9, 2020)

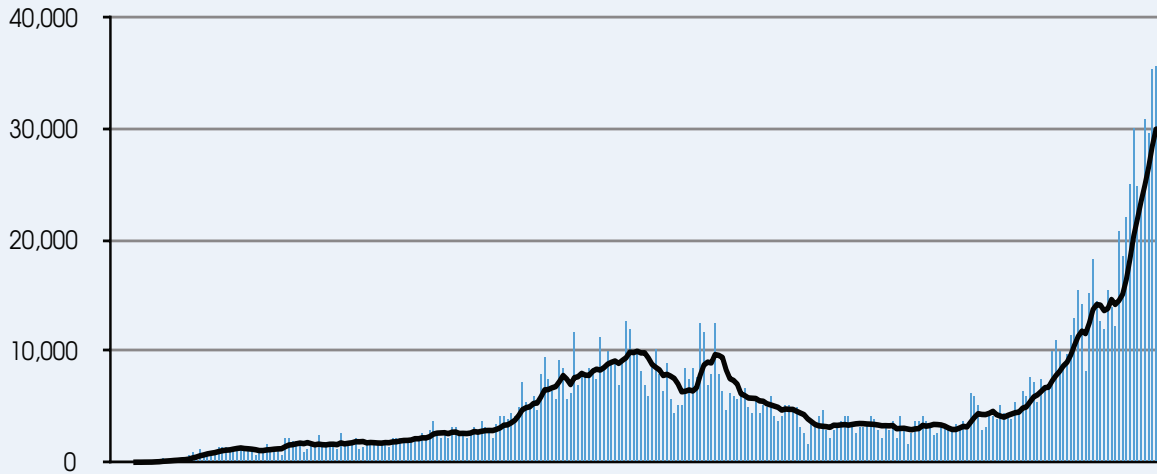


New York City Daily Deaths from Covid-19 with 7-Day Moving Avg. (March 1 through Dec. 9, 2020)

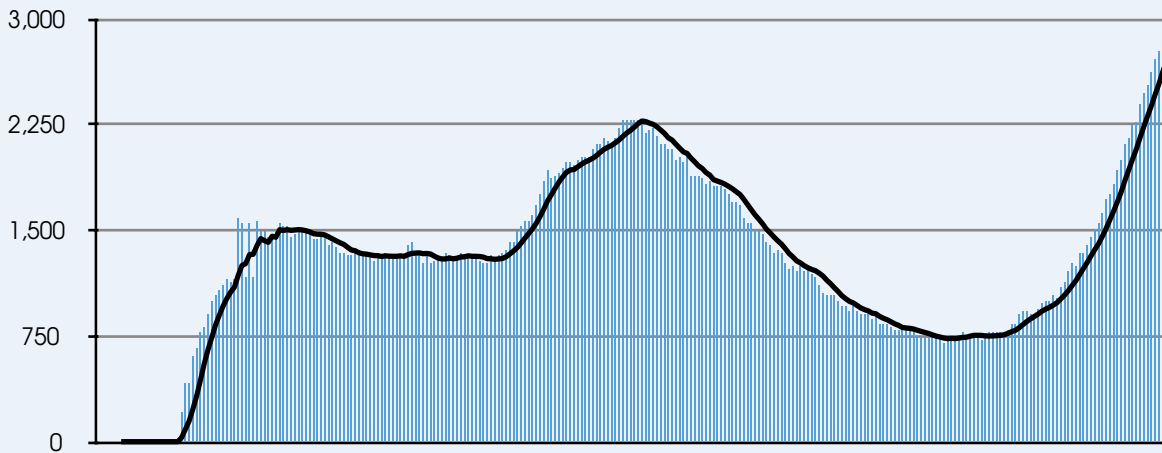


Source: NYC Department of Health and Mental Hygiene

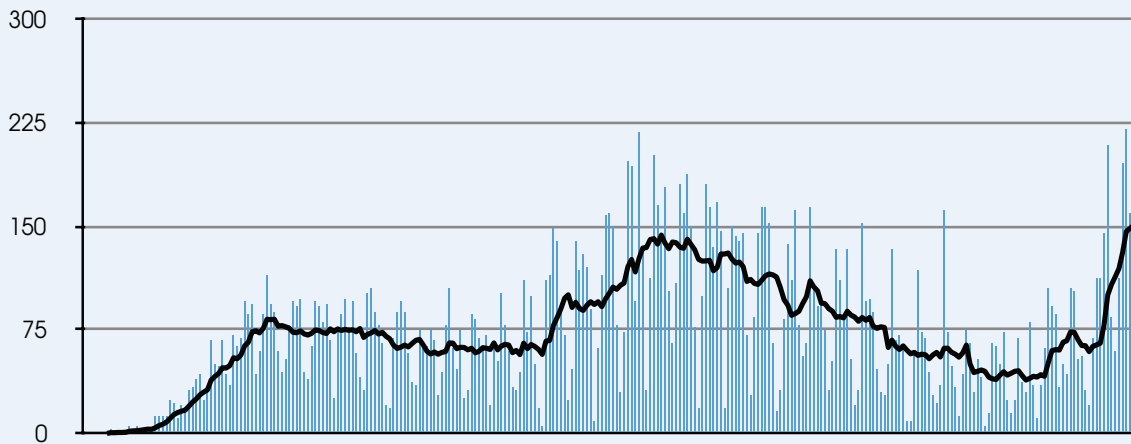
California Daily New Cases of Covid-19 with 7-Day Moving Avg. (March 5 through Dec. 13, 2020)



California ICU Patients with Covid-19 with 7-Day Moving Avg. (March 5 through Dec. 13, 2020)



California Daily Deaths from Covid-19 with 7-Day Moving Avg. (March 5 through Dec. 13, 2020)



Source: The Covid Tracking Project