

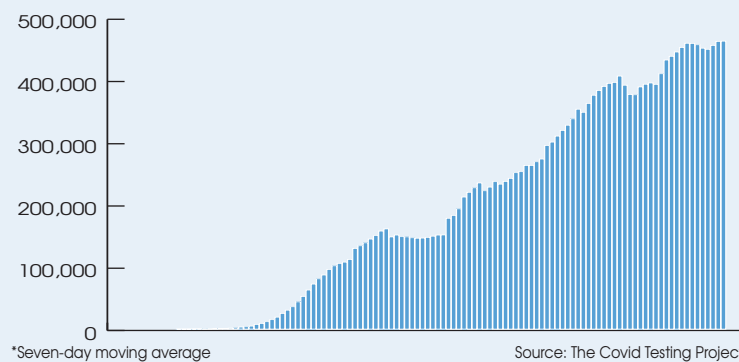
LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

Covid-19 Test Volumes Jump

Test and collection kit supply shortages that have limited labs from reaching their full Covid-19 diagnostic testing capacity have begun to ease resulting in a nearly 50% increase in test volume over the past month. Average U.S. volume for Covid-19 diagnostic testing reached 463,000 per day for the week ended June 14, up from 319,000 for the same time period in May, according to the Covid Tracking Project, which gathers state testing data. Meanwhile, most labs report ample

Daily U.S. Covid-19 Diagnostic Test Volume* (March 1 to June 14, 2020)



supplies and capacity to perform Covid-19 antibody testing, but demand has been much less than expected. *More details on page 10.*

Medicare Sets Good Rates For Covid-19 Testing

CMS has been very fair when establishing reimbursement rates for Covid-19 tests in an effort to encourage widespread diagnostic and antibody testing. Furthermore, private health plans are required to cover both diagnostic and antibody testing without member cost-sharing (copays or deductibles) as a result of the Families First Coronavirus Response Act (FFCRA). “Most private insurers have been uncharacteristically reasonable in establishing their rates and working with labs to fix claims processing errors for Covid-19 testing,” notes Lale White, Chairman & CEO at XIFIN Inc. (San Diego). *Full details on pages 3-4.*

Genova Diagnostics To Pay Up To \$43 Million To Settle False Claims Lawsuit

On April 27, the U.S. attorney for the Western District of North Carolina announced that Genova Diagnostics (Asheville, NC) had agreed to pay up to \$43 million to settle allegations that it had fraudulently billed the federal government for unnecessary lab test panels. The alleged misconduct was brought to light by whistleblower Darryl Landis, MD, former Chief Medical Officer at Genova. Landis will receive 15% of the settlement money — potentially almost \$6.5 million. *Cont’d on page 2.*

CONTENTS

HEADLINE NEWS

Covid Testing Jumps	1, 10
Good Rates for Covid Testing	1, 3-4
Genova Settles False Claims Lawsuit	1-2

SPOTLIGHT INTERVIEWS

Aculabs’ Peter Gudaitis	5-6
CellNetix’s Kathleen Fondren	7

CORONAVIRUS

Antibody Studies Show Covid-19 Less Deadly than Initially Believed	8-9
Covid-19 Diagnostic Test Market Share	10
Antibody Testing Fails to Take Off	11
Florida Antibody Testing Summary	11
Delta to Test All Employees	11

FINANCIAL

Lab Stocks Up 22% YTD	12
-----------------------------	----

STATISTICAL ADDENDUM

NYC Covid-19 Stats	13
Arizona Covid-19 Stats	14
Sweden’s Covid-19 Stats	15
Worldwide Covid-19 Stats	16

Genova Diagnostics To Pay Up To \$43 Million (cont'd from page 1)

Genova was originally founded in 1986 under the name Great Smokies Diagnostic Laboratory. The company is focused on marketing functional medicine test panels to progressive physicians who use Genova's tests to help create personalized treatment plans involving diet and exercise advice for patients with chronic conditions like irritable bowel syndrome and chronic fatigue syndrome.

Genova was acquired by the venture capital firms Nautic Partners and Ferrer Freeman & Company in 2010, which then sold their stake to Levine Leichtman Capital Partners, a Los Angeles-based private equity firm, in late 2013.

According to his whistleblower complaint, Landis was hired as Genova's CMO and tasked with developing medical necessity evidence for the company's test panels in July 2012. However, Landis was never able to complete any clinical studies demonstrating the medical necessity of Genova's test panels. Landis claims that he repeatedly raised concerns and warned Genova's management and owners that almost none of Genova's tests met the medical necessity criteria needed to bill Medicare. Landis contends that Genova dismissed his warnings as being "overly conservative." He was fired by Genova for alleged cause in December 2017 and filed his whistleblower complaint in May 2018.

The settlement agreement resolves allegations that Genova:

- Submitted claims to Medicare and Tricare for its IgG allergen, NutrEval and GI Effects test panels that were not medically necessary from January 2013 through August 2019.
- Billed improperly by appending Modifier 91 in order to bypass medically unlikely edits.
- Submitted claims for unbundled services related to its NutrEval panel tests.
- Violated the Stark Law through three phlebotomy agreements with referring physicians.

Under the settlement agreement, Genova will forfeit over \$17 million in payments from Medicare and Tricare. The company will also enter a five-year "corporate integrity agreement" involving an outside review organization. In addition, over the next five years, Genova will pay the government 13% of any net annual revenue above \$100 million and 20% of any asset sales over \$1 million. Those payments will be capped at \$26 million, creating a total potential liability of \$43 million.

"While we believed that Genova would have prevailed, we are pleased to avoid considerable distraction and expense by resolving this matter without any admission of guilt or wrongdoing," according to a statement from Genova.

Separately, a *Laboratory Economics*' analysis of Medicare Part B payment data shows that Genova submitted a total of \$99.6 million of Part B charges and received a total of \$44.8 million of Part B payments during the six-year period 2012-2017. During this period, Genova billed for an average of 47 tests per Part B patient and was paid an average of \$639.60 per patient.

Genova Diagnostics Medicare Part B Claims Stats, 2012-2017

	2012	2013	2014	2015	2016	2017	Totals 2012-2017
Total Part B Submitted Charges	\$14,617,442	\$16,023,673	\$17,813,278	\$19,675,119	\$16,723,171	\$14,757,306	\$99,609,990
Total Part B Payments	\$7,483,527	\$7,741,350	\$8,097,145	\$8,666,452	\$6,985,056	\$5,829,785	\$44,803,314
Part B Patients Served	10,024	10,534	11,301	12,043	12,863	13,284	70,049
Part B Test Volume	494,136	542,911	603,800	662,303	591,653	395,887	3,290,690
Avg. Payment per Part B Patient	\$746.56	\$734.89	\$716.50	\$719.63	\$543.03	\$438.86	\$639.60
Avg. Number of Tests per Part B Patient	49.3	51.5	53.4	55.0	46.0	29.8	47.0
Avg. Payment per Part B Test	\$15.14	\$14.26	\$13.41	\$13.09	\$11.81	\$14.73	\$13.62

Source: CMS/Medicare Part B Provider Utilization and Payment Data, 2012-2017

Medicare Sets Good Rates For Covid-19 Testing *(cont'd from page 1)*

High-Throughput Covid-19 Diagnostic Testing

Covid-19 diagnostic testing on high-throughput testing systems (200+ specimens per day; e.g., Roche cobas 6800/8800, Abbott m2000 System, Hologic Panther Fusion System, et al.) is billed using HCPCS U0003 or U0004 at a Medicare rate of \$100. XIFIN's White says that her firm has seen 89% of private insurance claims for U0003 and U0004 paid at or above Medicare's rate, and only 11% underpaid. She says that underpayment most commonly occurs with BCBS plans, which are frequently paying for high-throughput Covid-19 testing at the low-throughput rate of \$51.

Low-Throughput Covid-19 Diagnostic Testing

CMS has established two codes (HCPCS U0002 and CPT 87635) for low-throughput Covid-19 diagnostic testing systems (<200 specimens per day) and set reimbursement at \$51.31. Aetna and Cigna are paying equivalent rates, according to Scott Liff, President & CEO at Kellison & Company (Cleveland, OH). Similarly, UnitedHealthcare and many BCBS plans are allowing \$51.31, according to Deb Larson, Executive Vice President at TELCOR Inc. (Lincoln, NE). In addition, several big state Medicaid plans, including California, Illinois and New York, have set their fee-for-service rates for U0002/87635 equivalent to Medicare.

Covid-19 Antibody Testing

Medicare reimbursement for Covid-19 antibody testing has been set at \$45.23 for CPT 86328 (point-of-care tests) and \$42.13 for CPT 86769 (laboratory-based multi-step methods). These are very favorable rates when compared with other antibody test codes for infectious agents that are reimbursed by Medicare at rates between \$8.93 and \$19.35, according to Charles Root, PhD, President of CodeMap LLC (Chicago). He notes that labs testing for two antibodies (IgM and IgG) can bill CPT 86769 twice for total Medicare reimbursement of \$84.26.

Unfortunately, White says that private insurer reimbursement of Covid-19 antibody testing is more problematic. Most private payer claims for CPT 86769 are being reimbursed below the Medicare rate. For example, some BCBS plans are paying between \$12 and \$35, with an average of roughly \$20, according to White. Similarly, TELCOR's Larson has seen BCBS rates in the range of \$12 to \$20, while Kellison's Liff has seen rates of between \$15 and \$18 from Cigna.

In addition, some private insurers have taken the position that antibody testing should not be covered if it's part of an employer-based testing effort for bringing their staff safely back to work, even if the testing is voluntary and performed under a doctor's order. This flies in the face of the CARES Act, which is intended to promote both Covid-19 diagnostic and antibody testing for anyone that wants it, notes White.

Claims Denial Rates for Covid-19 Testing

Early on in the pandemic (March/April), White says that XIFIN was seeing denials and balance bill errors occurring on about 22% of the Covid-19 test claims it processed. The most common denial and adjudication errors involved medical necessity denials and improper processing of patient co-pays and deductibles.

However, White says that most payers have readily acknowledged their adjudication errors, made corrections and reprocessed claims with very few requesting a resubmission.

On current claims through the end of May, White says that initial denial rates have fallen to 7% with co-pay/deductible errors at less than 1%. "We expect that 7% medical necessity denial rate to get down to 4% to 5% after we make some calls to correct the remaining denial adjudication errors."

Similarly, Larson says that TELCOR is currently seeing initial denial rates of 5% to 9% on Covid-19 test claims with the primary source of denials related to member insurance coverage eligibility.

Challenges for Out-of-Network Labs

White notes that one issue that has not been resolved is the continuation of BCBS payer policies that reimburse patients directly for out-of-network (OON) lab test claims. This forces OON labs performing Covid-19 testing to seek payment from patients. “With bad debt rates as high as 50% on direct patient billing and all the added costs involved with identifying a direct patient payment, it is not prudent for the Blues to take a position of penalizing labs that are OON during a time when extensive testing capacity is being demanded at the federal, state and local level for management of the pandemic,” observes White.

Specimen Collection Rates for Covid-19

On March 30, CMS announced the creation of new Covid-19 specimen collection HCPCS codes (G2023 and G2024) at very favorable rates.

HCPCS G2023 is intended for independent labs that collect Covid-19 specimens (by any specimen source) from homebound or non-hospital patients. Medicare reimbursement has been set at \$23.46.

HCPCS G2024 is intended for independent labs that collect Covid-19 specimens (by any specimen source) from patients in a nursing home or on behalf of a home health agency. Medicare reimbursement has been set at \$25.46.

CMS says that these new specimen collection codes will remain in effect until it has determined that the Covid-19 pandemic is over.

The rates for G2023 and G2024 are far above Medicare’s existing \$5 rate for G0471 paid to labs for non-Covid-19 blood collection services provided to nursing home patients or on behalf of a home health agency.

However, the catch is that nearly all Covid-19 diagnostic test samples are nasal swabs that are collected by nurses, not lab-employed phlebotomists (see page 6 for more).

The new Covid-19 specimen collection codes do apply to lab-employed phlebotomists that collect blood samples for Covid-19 antibody testing from nursing home or homebound patients. However, demand for antibody testing has been weak to date.

Medicare Rates for Covid-19 Testing

Code	Description	Rate
U0002	Covid-19 diagnostic test, any technique (low-throughput)	\$51.31
87635	Covid-19 PCR-based diagnostic test (low throughput)	\$51.31
U0003	Covid-19 PCR-based diagnostic test (high-throughput)	\$100.00
U0004	Covid-19 diagnostic test, any technique (high-throughput)	\$100.00
86328	Covid-19 antibody(ies) single-step method (i.e., point-of-care testing)	\$45.23
86769	Covid-19 antibody testing with multi-step methods (i.e., laboratory-based)	\$42.13
G2023	Specimen collection for Covid-19 from homebound or non-hospital inpatients, any specimen source	\$23.46
G2024	Specimen collection for Covid-19 from patient in nursing home or by a laboratory on behalf of a home health agency, any specimen source	\$25.46

Source: CodeMap and CMS

Spotlight Interview with Aculabs President Peter Gudaitis

Aculabs (East Brunswick, NJ), which has 300 employees and services almost 500 long-term care facilities in New Jersey, Eastern Pennsylvania, Maryland and Delaware, is at the forefront of the Covid-19 pandemic. *Laboratory Economics* recently spoke with Aculabs owner, Peter Gudaitis.



Peter Gudaitis

What happened to your laboratory's testing volumes after mid-March?

As a biomedical laboratory which specializes in nursing homes, we typically do routine testing. With the onset of Covid, we saw a disproportionate decrease in tests like Vitamin D and Glycohemoglobin, and by contrast we saw a tremendous increase—upwards of 200%—in D-dimer, blood cultures and procalcitonin. Our accessioning volume is up, largely due to Covid/PCR testing, but routine testing is down roughly 10%.

When did Aculabs begin PCR-based Covid-19 testing and which analyzer system do you use?

Aculabs performed its first PCR test for CoV2 on April 6th. We were fortunate to have a Becton Dickinson BD Max. Although we have had struggles getting testing kits (in addition to specimen collection kits) we try to make the best of it. The BD Max is very easy to use, but with the recent call from the various state health departments, it doesn't have the throughput we need, which is why we have partnered with LabCorp to ensure that our residents' needs are met.

Aculabs performs roughly 170 Covid-19 tests in-house on a daily basis. This number could go as high as 360. However, Becton Dickinson continues to have supply chain issues which limit our testing. We are currently sending out about 1,500 specimens per day, seven days a week, to LabCorp.

Our volume peak thus far came on May 22, when Aculabs performed 200 Covid-19 tests in-house and sent out another 3,081 to LabCorp for a total of 3,281.

We have considered other platforms, but I believe the best way to meet the needs of the residents is through a nursing home lab/larger reference lab relationship. As states are requiring more and more testing, small labs are under tremendous financial constraints, and spending millions of dollars for a large volume high throughput testing platform may not be a wise decision. That is not to say that we are not working on expanding our offerings—about a month ago we purchased and validated a BioFire Torch system—but we have adopted a more conservative path.

What is your current demand for PCR-based Covid-19 testing?

As previously mentioned, on average, we're getting about 1,500 orders for Covid-19 per day, most of which is sent to LabCorp. In the various states we service, the call for mandated testing has been a driving force in the volumes we are seeing. It started with New York, but New Jersey immediately followed suit, and Pennsylvania did not lag far behind. With weekly mandated testing, we expect to see the volume remain fairly consistent. Despite the increase in volume, we have seen a decrease and stabilization of turnaround time for results. We are typically seeing results between 24 and 36 hours.

Is Aculabs doing Covid-19 antibody testing?

We are. We started with Roche Elecsys total antibody on the cobas 602 and 801. We also have an Abbott Architect 1000 and two Siemens analyzers. We could perform about 3,000 antibody tests per day, but the demand isn't there. The less scrupulous "test manufacturers," anxious to rush a product to market (regardless of sensitivity and specificity), put a black mark on the

concept of antibody testing. My colleagues at ACLA and I are working to correct this. With a surprising number of asymptomatic positives, there is a place for antibody testing, and it will prove to be a useful asset in the clinicians' tool box.

Are you starting to see non-Covid testing increase?

Slowly but surely it is. The nursing homes in New Jersey took a big hit from Covid, but I believe we will eventually see non-Covid testing return to normal.

Have you had to revise your expected revenues for the year because of the pandemic?

Being an owner/operator who is involved in all aspects of the laboratory, I have been extremely busy. I haven't had a chance to dive deep into it, but overall, we anticipate revenue to increase while costs will be right there with it. Unexpected costs, such as PPE and hazard pay, will certainly affect the bottom line.

Will Medicare's new code (G2024/\$25.46) for specimen collection for Covid-19 testing from patients in nursing homes be helpful?

I believe the intent to help the nursing home laboratory was there. However, the policy was a bit off the mark. Phlebotomists are not trained to collect nasopharyngeal swabs from nursing home residents. The collection procedure of this nature is something that a LPN or RN would perform and outside the scope of practice for a phlebotomist. No laboratory I can think of is actually performing and therefore billing for this service.

A suggestion was made by ACLA to CMS Administrator Seema Verma to modify the collection definition to include the "gathering" of the specimen as opposed to the "collection." It would prove especially beneficial in improving access because as it stands now the nursing home laboratory, who incurs all of the cost of shipping supplies out, gathering, transporting, and processing (data entry and labelling) of the specimens are handing it off to the larger laboratories who ultimately bill and are paid for the testing and the nursing home lab receives very little to nothing in return.

An estimated 30% to 50% of Covid-19 deaths in the U.S. are comprised of nursing home patients. Do you have any policy recommendations that could help limit Covid-19 outbreaks at nursing homes?

There are three ways to help. Empowering the laboratories that provide services to the nursing home industry would pay off immensely. Most of the nursing home labs rely on larger reference laboratories for testing, but by placing testing equipment in these labs it would improve turnaround time and the speed at which clinicians respond. The ability to test quickly allows clinicians to respond quickly.

In addition, a standard infection control protocol would improve patient safety and help identify issues. A statistical approach with incidence triggers as opposed to prevalence triggers makes more sense.

And lastly, we, as an industry, need to work with CDC and the various State Health Departments to help improve tracking and surveillance. The reporting process now is far too cumbersome and disjointed. The clock is ticking and the next flu season is only a few short months away.

What do you believe the long-term effect of Covid-19 will be on Aculabs?

The need for additional PPE won't diminish, so there will be additional costs moving forward. As we move into the summer months, we expect to see testing volumes normalize, but this isn't the last we will see of Covid-19. We are expecting a resurgence with the upcoming flu season.

Spotlight Interview With CellNetix's CEO Kathleen Fondren

CellNetix Pathology and Laboratories (Seattle) was preparing to move into its new 46,000-square-foot operational hub in the Greater Seattle suburb of Tukwila when Covid-19 hit the United States in January. *Laboratory Economics* recently spoke with CEO Kathleen Fondren about the effect of the pandemic on the lab.



Kathleen
Fondren

What happened to your laboratory's testing volumes after mid-March?

They decreased quite materially based on not having any elective surgeries, as well as colonoscopies and endoscopies. Our volumes probably dropped between 40% and 50%, but they have started coming back. We've probably seen a 25% to 30% return. I think there will be a slower return to 100% because not everyone is comfortable going to their doctor yet.

Is CellNetix performing PCR-based Covid-19 diagnostic testing?

We are not currently doing Covid-19 testing. We are evaluating which platform would be best for us. We didn't have the right existing platforms for the Roche and Hologic tests, and with so many tests coming on the market, we wanted to wait a little bit to let things shake out. We're also in the midst of relocation to our new laboratory, but we are hoping to bring up the testing on one of our in-house platforms.

Are you doing Covid-19 antibody testing?

No, we don't have any serum-based testing for Covid right now, but we are looking into antigen testing.

Have you had difficulties in getting PPE and other supplies?

We had some difficulties accessing PPE, but we were able to get some through the county stockpile and through our hospital partners.

What are you projecting in terms of revenues and growth for the year?

We're hoping to regain a lot of it back, so it's hard to tell at this point. We are kind of taking it month to month. I am hoping by the end of the year, we'll come within 10% of budget, but we don't expect to hit our growth targets. We're expecting flat or slightly under for the year.

What has the impact on employees been?

We have 350 employees and we're staffing to our volume needs, but we had no layoffs and no furloughs. We worked with employees to take advantage of payroll protection programs out there. We also have several people working from home and have quickly learned this can be very efficient for some areas.

As far as safety, we are following all the CDC guidelines. We put in sneeze guards in the lab. If a department couldn't be set up so that staff were six feet apart, we adjusted shifts. We clean every two hours. And we have had outside companies come in to do deep cleaning.

When do you now plan to make the move into your new laboratory building?

We are in the process of relocating and expect to be totally moved by June 22.

Has digital pathology been helpful during the current crisis?

Yes, we have leaned on it a bit more with IHC.

Antibody Studies Show Covid-19 Less Deadly Than Initially Believed

An analysis of 34 different Covid-19 seroprevalence studies (see table, page 9) from around the world indicates that roughly 3% to 10% of the world's population had developed antibodies to the virus by the end of April. This is far higher than the official number of worldwide confirmed cases, which was 3.1 million cases, or 0.04% of the world's population, at the end of April, according to figures from the World Health Organization.

The higher prevalence means that the infection fatality rate (IFR), the probability of dying for a person who is infected, most likely falls within the range of between 0.2% and 1%. This is far worse than the seasonal flu (IFR = ~0.1%), but less than the crude case fatality rate of 3.4% that the WHO focused on during the early stages of the pandemic in March.

However, even an IFR of only 0.25% could result in several hundred thousand American deaths. Assuming that 30% to 60% of the U.S. population (331 million) ultimately gets Covid-19, and that 0.25% of those infected die, would suggest that the virus might ultimately reach a death toll of between 250,000 and 500,000.

New CDC Estimates Point to IFR of 0.26%

The Centers for Disease Control and Prevention (CDC) recently reported that its “best estimate” for the fatality rate among Americans with Covid-19 symptoms is 0.4%. The CDC also estimates that 35% of people infected by the Covid-19 virus never develop symptoms. The CDC's numbers imply an overall IFR, including both symptomatic and asymptomatic patients, of only 0.26% (0.4% x 65% = 0.26%). This falls within the range of the 34 antibody studies analyzed by *Laboratory Economics*. The CDC's estimates were contained in a report titled *COVID-19 Pandemic Planning Scenarios*.

Elderly At Much Higher Risk

The clearest example of the lethality of Covid-19 on the elderly is a comparison of the outbreak on the Diamond Princess Cruise Ship versus the USS Theodore Roosevelt aircraft carrier.

The Diamond Princess had a total of 3,711 passengers and crew onboard. The overall median age was 58 and 33% were 70 or older. An outbreak started in February and there were 712 people (19.2%) who tested positive for Covid-19, including 567 passengers and 145 crew members. Thirteen people died. All deaths were among passengers age 70 or older. The overall infection fatality rate was 1.8% (13 deaths/712 cases).

A similar Covid-19 outbreak began on the USS Theodore Roosevelt during a port call at Da Nang, Vietnam in early March. The average age of the 4,845 enlisted sailors and officers on the ship was approximately 30. Over the course of a few weeks, 1,273 (26%) got the virus. Among those contracting Covid-19, there were just seven hospitalized and only one death—an officer, age 41, who died on April 13. The overall infection fatality rate was 0.08% (1 deaths/1,273 cases).

Separately, the CDC's report has an implied IFR for Covid-19 by age range as follows: 0.03% for age 0-49; 0.13% for age 50-64; and 0.85% for age 65+.

Has New York City Reached Herd Immunity?

The number of daily new cases, hospitalizations and deaths from Covid-19 in New York City has fallen dramatically since peaking in late April (see page 13). This may be because New York City, despite its lockdown, is approaching herd immunity.

A New York State Department of Health antibody testing survey of 15,101 people at 99 grocery stores throughout the state in late April found that 14% had contracted Covid-19. The incidence was highest in New York City (22.7%). (See *Cumulative Incidence and Diagnosis of SARS-CoV-2 Infection in New York*. medRxiv 5/25/2020.)

A separate antibody study was conducted by Sherman Abrams Laboratory (Brooklyn, NY). A total of 28,523 patient blood samples were collected at primary care offices and urgent care centers throughout New York City in May through early June. Of these, 12,424 were Covid-19 IgG positive indicating a 44% positivity rate in the study’s patient population, which reflects the extent of the pandemic in New York City. The age groups with the highest prevalence were ages 16-20 (57% positive) and ages 11-15 (56% positive). (See *SARS-CoV-2 IgG Antibody Responses in New York City*. medRxiv 6/7/2020.)

After adjusting these study results for an average of 21 days from Covid-19 onset to IgG antibody detection, and assuming further spread of the virus in May and June, suggests that more than 50% of New York City’s residents may currently have antibody protection.

Covid-19 Antibody Study Results

Study Author/ Location	Survey Date	Sample Size	Prevalence	IFR
Institute of Health Carlos III/Spain	May 18-June 1	63,564	5.2%	1.10%
Softbank/Japan	May 12-June 8	44,066	0.4%	0.16%
Sherman Abrams Laboratory/New York City	May/early June	28,523	43.6%	0.60%
Universidade Federal de Pelotas/Brazil	May 15-May 22	24,995	1.6%	0.30%
University at Albany School of Public Health/New York State	April 19-28	15,101	14.0%	0.68%
Aarhus University Hospital/Denmark	April 6-17	9,496	1.7%	0.38%
Sanquin Research/Netherlands	April 1-15	7,361	2.7%	0.68%
University of Washington/Boise, Idaho	late April	4,856	1.8%	0.16%
U.S. Navy/USS Theodore Roosevelt	March/April	4,845	26.3%	0.08%
Indiana University/Indiana	April 25-May 1	4,600	2.8%	0.58%
Universidade Federal de Pelotas/Rio Grande do Sul, Brazil	April 25-27	4,500	30.9%	0.14%
Diamond Princess Cruise Ship/Japan	February	3,711	19.2%	1.83%
Stanford University School of Medicine/Santa Clara County, CA	April 2-3	3,300	2.6%	0.18%
Hemorio/Rio de Janeiro State, Brazil	April 14-27	2,857	3.3%	0.22%
Cape Girardeau County Public Health Ctr/Cape Girardeau, MO	mid-May	1,845	0.9%	0.29%
Luxembourg Institute of Health/Luxembourg	April 15-May 5	1,807	2.1%	0.73%
Tel Aviv University/Israel	April	1,700	2.5%	0.14%
University of Split/Croatia	April 23-28	1,494	1.3%	0.15%
CR & WISCO General Hospital/Wuhan, China	April 3-15	1,401	10.0%	0.35%
University of Miami/Miami-Dade County	April	1,400	6.0%	0.17%
SciLifeLab/KTH/Sweden	late April	1,104	5.0%	0.52%
Fred Hutchinson Cancer Rsrch Center/Seattle Children’s Hospital	March 3-April 24	1,076	0.9%	0.00%
Navitas Clinic/Tokyo, Japan	April 21-May 20	1,071	3.8%	0.04%
Philipps University Marburg/Frankfurt, Germany	April 6-14	1,000	0.6%	0.26%
University of California, San Francisco/Bay Area, California	March	1,000	0.1%	0.15%
Kobe City Medical Center General Hospital/Kobe, Japan	March 31-April 7	1,000	2.7%	0.02%
University of Bonn/Gangelt, Germany	March 30-April 6	919	20.0%	0.28%
USC and L.A. County Department of Public Health/Los Angeles	April 10-14	863	4.7%	0.20%
University of Milan/Milan, Italy	Feb. 24-April 8	789	5.2%	0.86%
Institut Pasteur/Northern France	March 30-April 4	661	25.9%	0.04%
Geneva University Hospitals/Geneva, Switzerland	April 20-27	576	9.7%	0.50%
Guilan University/Iran	April	551	33.0%	0.08%
University of Oxford/Scotland	March 21-23	500	1.2%	0.07%
Massachusetts General Hospital/Chelsea, MA	April 14-15	200	31.5%	0.31%
Unweighted Average			9.5%	0.36%
Weighted Average			9.8%	0.57%
Median			3.6%	0.24%

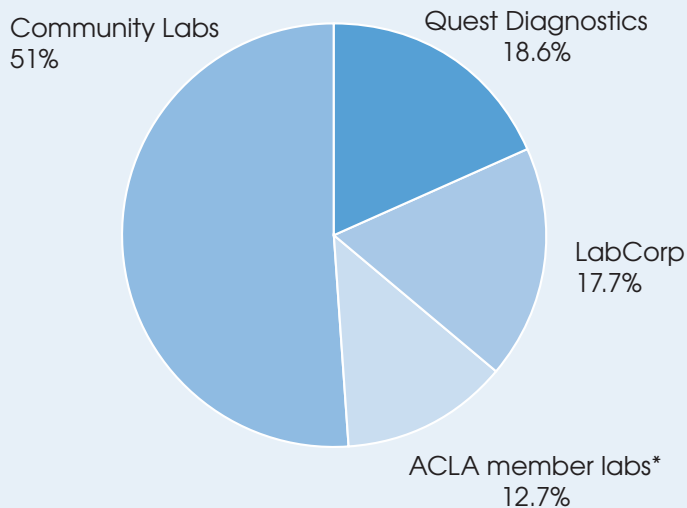
Source: Laboratory Economics from study reports and *The Infection Fatality Rate of Covid-19 Inferred from Seroprevalence Data*. medRxiv 6/8/2020

Covid-19 Test Volumes Jump *(cont'd from page 1)*

The nation's largest commercial labs, Quest Diagnostics and LabCorp, are each currently performing about 85,000 Covid-19 diagnostic tests per day and each has spare capacity to perform an additional 20,000 tests per day.

Other ACLA member labs (ARUP, BioReference, Mayo, Sonic, et al.) are currently performing a combined total of approximately 59,000 Covid-19 diagnostic tests per day.

Covid-19 Diagnostic Test Volume Market Share (as of mid-June 2020)



*ACLA member labs including Aculabs, Aegis Sciences, ARUP, Biodesix, BioReference Labs, Exact Sciences, Inform Diagnostics, Mayo Clinic Labs, NeoGenomics and Sonic Healthcare

Source: *Laboratory Economics* from the Covid Tracking Project, ACLA, LabCorp and Quest Diagnostics

Community labs (hospitals and independent labs) are performing a total of approximately 236,000 Covid-19 diagnostic tests per day, representing 51% of total U.S. volumes. Their volumes would be much higher, but many still report supply constraints that are forcing them to send excess demand to a commercial lab.

Over time, as Covid-19 test and collection kit supply constraints ease, community labs' share of Covid-19 testing should increase.

Estimating the Market Size for Covid-19 Testing

The U.S. market for Covid-19 diagnostic testing could reach as much as \$14.7 billion over the one-year period from June 1, 2020 through May 31, 2021, estimates *Laboratory Economics*. This esti-

mate is based on an assumption of an average 500,000 Covid-19 diagnostic tests per day with a 5% claim denial rate.

Reimbursement is estimated at an average of \$85 per test, accounting for the fact that most but not all private insurers are paying the Medicare rate of \$100 per high-volume test. A small portion of testing is also being performed at the low-volume rate of \$51 per test. (500,000 tests per day x 365 days minus 5% denials x \$85 per test=\$14.7 billion.)

Assuming that Quest and LabCorp each obtain a 15% share of the market suggests they could each add more than \$2 billion of revenue from Covid-19 diagnostic testing over the next 12 months.

Copyright warning and notice: It is a violation of federal copyright law to reproduce or distribute all or part of this publication to anyone (including but not limited to others in the same company or group) by any means, including but not limited to photocopying, printing, faxing, scanning, e-mailing and Web-site posting. If you need access to multiple copies of our valuable reports then take advantage of our attractive bulk discounts. Please contact us for specific rates. Phone: 845-463-0080.

Not Much Demand For Covid-19 Antibody Testing So Far

Demand for Covid-19 antibody testing has so far been surprisingly low. Most employers don't want to take on the added expense of antibody testing and some private insurance plans contend that this testing is not medically necessary if done for return-to-work programs.

There are not yet any national statistics on Covid-19 antibody testing. However, the Florida Department of Health (FDH) has released detailed information of the state's antibody test volumes, positivity rate and market share among laboratories.

Florida's population is 21.5 million. As of June 12, FDH reports that 181,037 laboratory-based antibody tests had been performed plus another 10,903 point-of-care tests. POCTs are performed at five drive-through testing sites using the FDA-cleared Cellex qSARS-CoV-2 IgG/IgM Rapid Test. Overall, there have been 8,335 positive tests (4.3%) out of the total 191,940 tests performed. The positivity rate for laboratory-based antibody testing is 4.4%, while POCT positivity has been 4.0%.

To date, Quest Diagnostics has performed 116,000 antibody tests in Florida, giving it a 60% share. LabCorp has performed 47,000 tests for a 24% share and the Cellex POCT has a 6% share.

Quest Diagnostics

As of June 8, Quest reports that it has performed a nationwide total of 1.65 million Covid-19 antibody tests. Its current average volume is 22,000 Covid-19 antibody tests per day and it has the capacity to perform up to 200,000 tests per day.

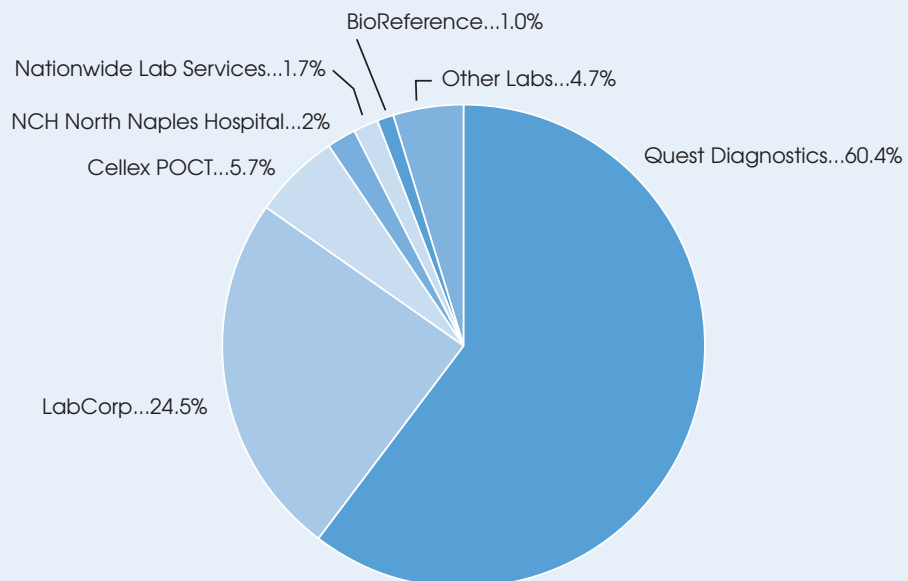
LabCorp

As of June 12, LabCorp reports that it has performed a nationwide total of 1.2 million Covid-19 antibody tests. Its current average volume is 26,000 Covid-19 antibody tests per day and it has the capacity to perform up to 300,000 tests per day.

Delta To Test All Employees for Covid-19

Delta Airlines, which has 90,000 employees worldwide, has announced it will test all its employees for both active Covid-19 and its antibodies. Delta has contracted with Quest Diagnostics and Mayo Clinic Labs to perform the testing, which will begin in Minneapolis, followed by Atlanta, Detroit and New York. Delta has had 10 employees die due to the virus through early June.

Covid-19 Antibody Test Volume Market Share in Florida



Source: Florida Department of Health (as of June 12, 2020)

Lab Stocks Up 22% Year To Date

Twenty lab stocks have risen by an unweighted average of 22% year to date through June 12. In comparison, the S&P 500 Index is down 6% so far this year. The top-performing lab stocks thus far in 2020 are Aspira Women's Health (formerly named Vermillion), up 394%; Biocept, up 91%; and Opko Health, up 69%. Shares of LabCorp are down 1%, while Quest Diagnostics is up 4%.

Company (ticker)	Stock Price 6/12/20	Stock Price 12/31/19	2020 Price Change	Enterprise Value (\$ mill)	Enterp Value/Revenue	Enterp Value/EBITDA
LabCorp (LH)	\$167.73	\$169.17	-1%	\$24,530	2.1	17.4
Quest Diagnostics (DGX)	110.60	106.79	4%	19,080	2.5	12.8
Sonic Healthcare (SHL.AX)*	28.07	28.75	-2%	17,190	2.6	13.2
Exact Sciences (EXAS)	85.37	92.48	-8%	14,130	13.3	NA
Guardant Health (GH)	77.09	78.14	-1%	7,080	28.9	NA
Natera (NTRA)	40.93	33.69	21%	2,990	9.1	NA
NeoGenomics (NEO)	27.02	29.25	-8%	2,910	6.9	80.7
Invitae (NVTA)	16.17	16.13	0%	2,200	9.1	NA
Opko Health (OPK)	2.48	1.47	69%	2,140	2.4	NA
CareDx (CDNA)	31.51	21.57	46%	1,450	10.4	NA
Myriad Genetics (MYGN)	12.01	27.23	-56%	1,340	1.8	NA
Veracyte (VCYT)	24.28	27.92	-13%	1,180	9.7	NA
Castle Biosciences (CSTL)	37.02	34.37	8%	563	9.3	47.1
Aspira Women's Health (VRML)	4.00	0.81	394%	394	79.5	NA
DermTech Inc. (DMTK)	12.68	12.40	2%	175	35.5	NA
Exagen (XGN)	12.45	25.40	-51%	103	2.5	NA
Enzo Biochem (ENZ)	2.25	2.63	-14%	100	1.3	NA
Biocept (BIOC)	0.55	0.29	91%	45	7.6	NA
Psychedics (PMD)	5.51	9.15	-40%	30	0.9	7.1
Interpace Biosciences (IDXG)	5.17	5.00	3%	18	0.7	NA
Unweighted Averages			22%	\$97,648	11.8	29.7

*Sonic Healthcare's figures are in Australian dollars

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

Subscribe to Laboratory Economics

YES! Please enter my subscription to *Laboratory Economics* at \$395 for one year. Subscription includes 12 monthly issues sent electronically plus access to all back issues at www.laboratoryeconomics.com/archive.

Check enclosed
(payable to *Laboratory Economics*)

Charge my: MC Amex Visa (circle one)

Card # _____

Name _____

Exp. Date _____ Security Code: _____

Title _____

Cardholder's name _____

Company _____

Signature _____

Mailing Address _____

Billing address _____

City, State, Zip _____

Phone _____

Fax _____

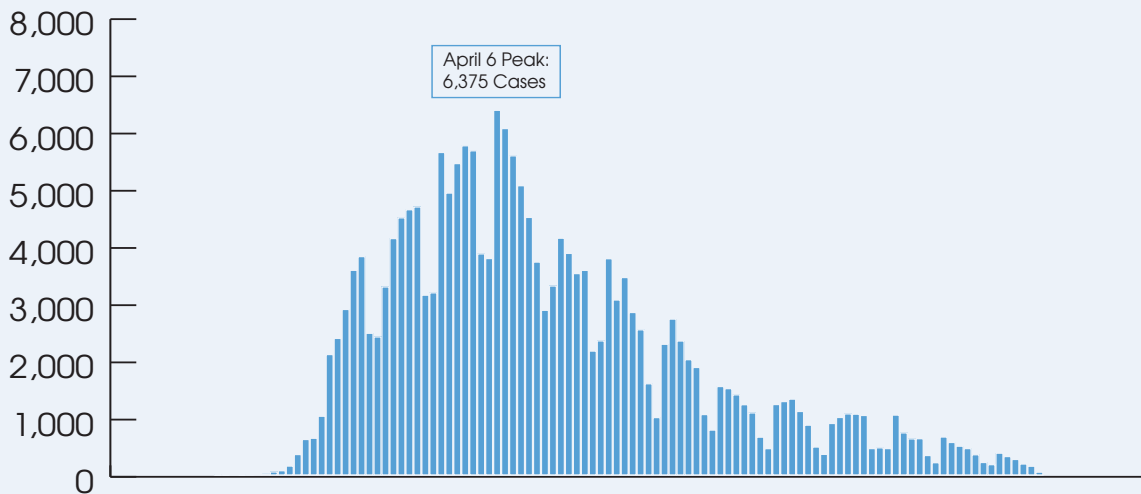
e-mail address _____

Mail To: Laboratory Economics, 195 Kingwood Park, Poughkeepsie, NY 12601;
Fax order to 845-463-0470; or call 845-463-0080 to order via credit card.

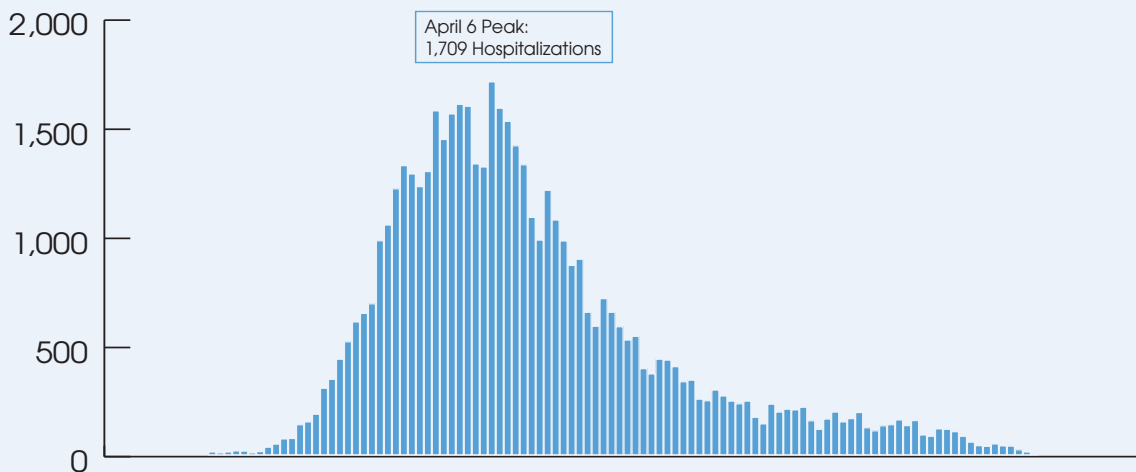
CC2020

100% Satisfaction Guaranteed! If at anytime you become dissatisfied with your subscription to *Laboratory Economics* drop me an e-mail and I'll send you a refund for all unmailed issues of your subscription, no questions asked.
Jondavid Klipp, labreporter@aol.com

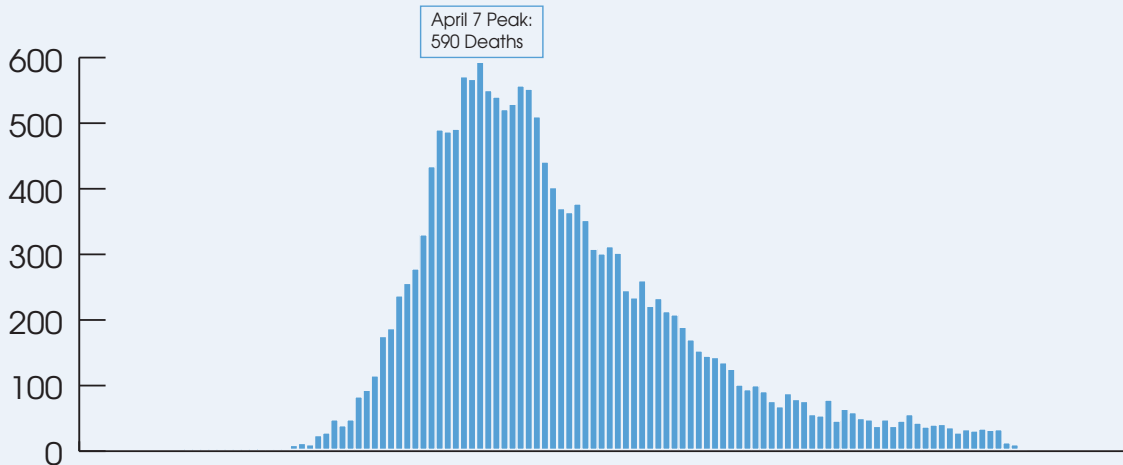
New York City Daily New Cases of Covid-19 (March 2 through June 13, 2020)



New York City Daily New Hospitalizations from Covid-19 (March 2 through June 13, 2020)

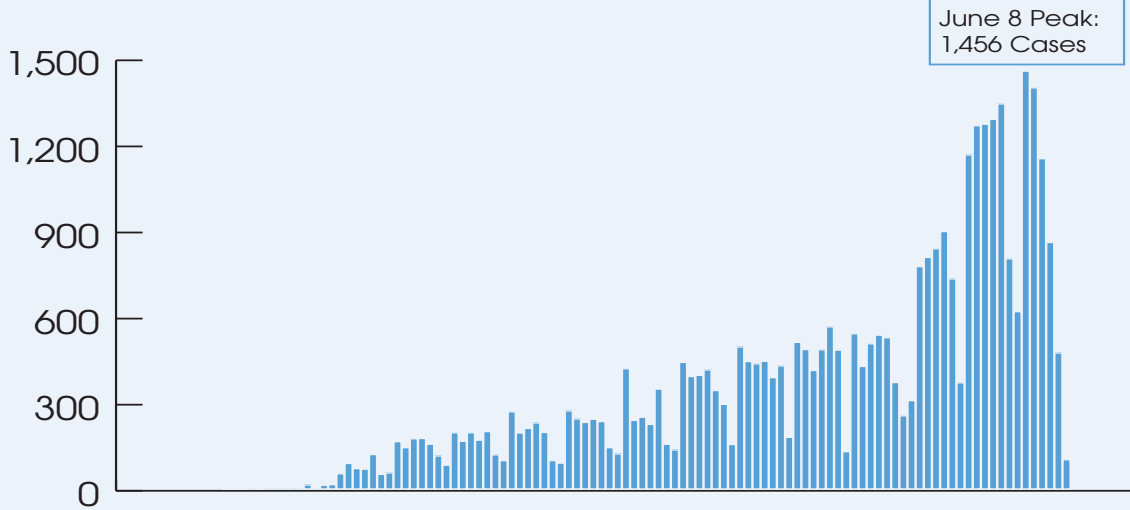


New York City Daily Deaths from Covid-19 (March 2 through June 13, 2020)

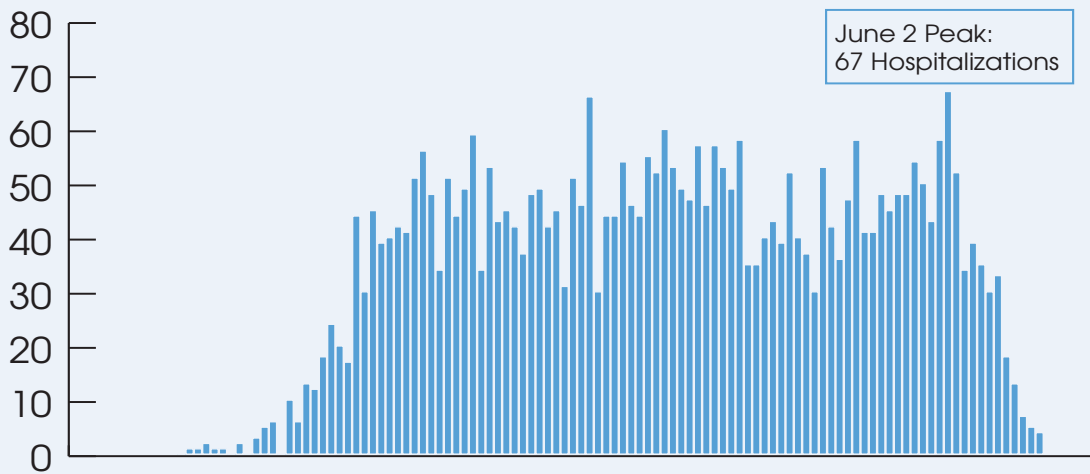


Source: NYC Department of Health and Mental Hygiene

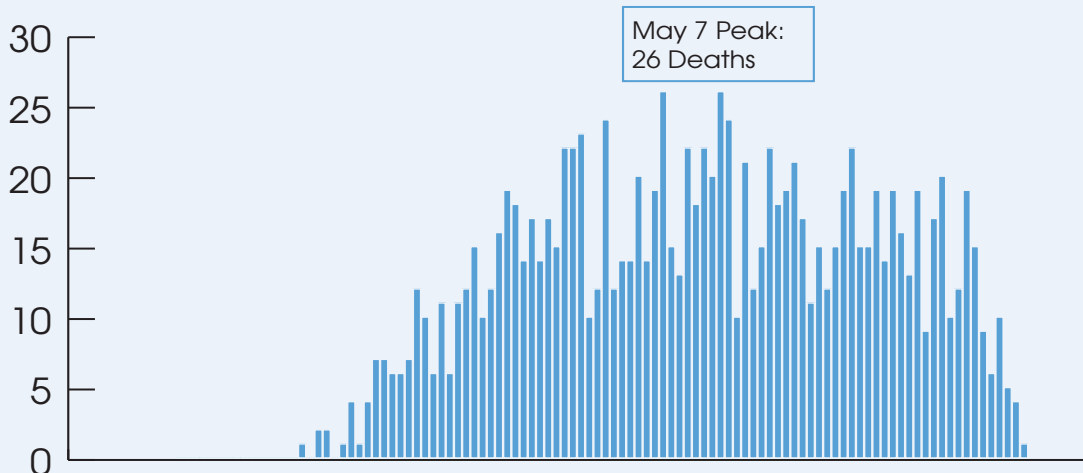
Arizona Daily New Cases of Covid-19 (March 2 through June 13, 2020)



Arizona Daily New Hospitalizations from Covid-19 (March 2 through June 13, 2020)



Arizona Daily Deaths from Covid-19 (March 2 through June 13, 2020)



Source: Arizona Department of Health Services

Sweden Maintains Its Long-Term Covid-19 Strategy

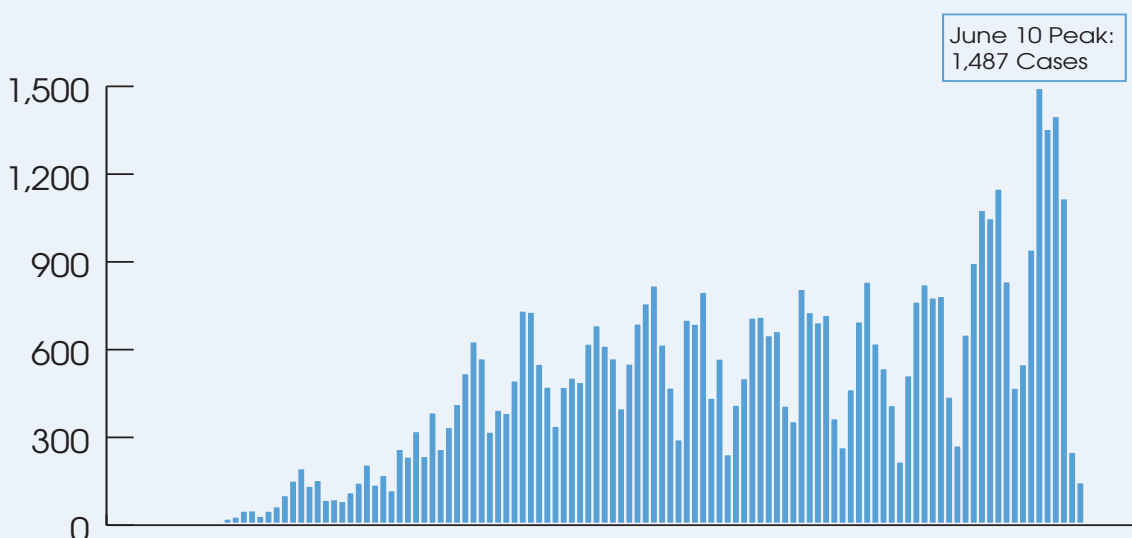
Sweden reached a new peak in daily new Covid-19 cases (1,487) on June 10 due to an increase in testing.

The nation's Chief Epidemiologist, Anders Tegnell, MD, PhD, recently said that, in hindsight, Sweden should have done more testing and done a better job of keeping the virus out of its nursing homes. A total of 4,891 Swedes have died from Covid-19, including 4,335 people age 70 or older.

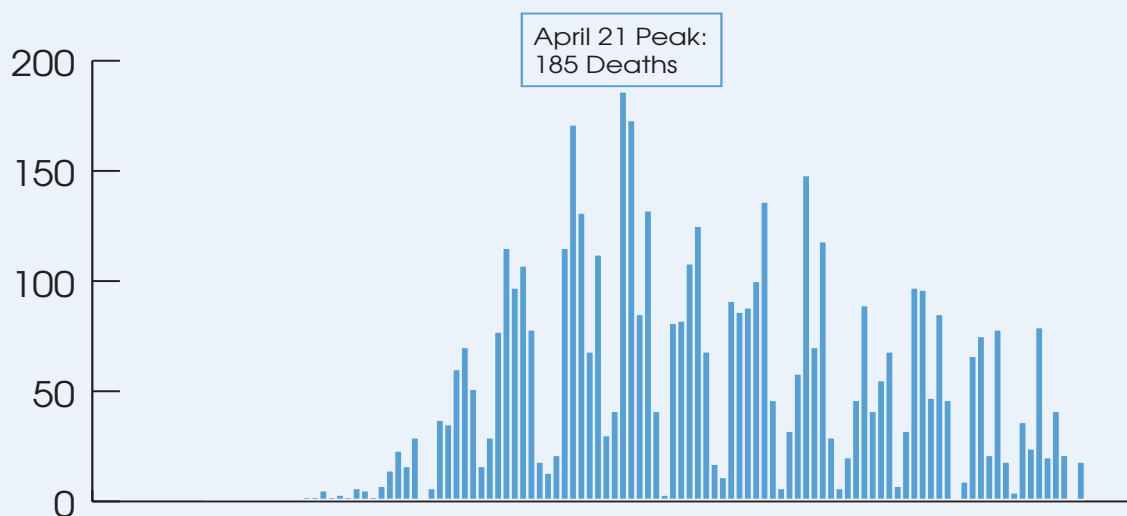
Sweden has not had a strict lockdown like most other countries.

In a June 14 interview on state broadcaster SVT, Sweden's Prime Minister Lofven said that "it's too early to draw any definitive conclusions about the success of our strategy." Sweden's less-restrictive strategy toward Covid-19 is meant to be kept in place for a long time.

Sweden's Daily New Cases of Covid-19 (March 2 through June 15, 2020)



Sweden's Daily Deaths from Covid-19 (March 2 through June 15, 2020)



Source: Worldometer and www.folkhalsomyndigheten.se

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

Country	Population (millions)	Urban Pop %	Median Age	Total Tests	Total Cases	Total Deaths	Deaths/1M Pop
Belgium	11.6	98%	42	1,045,014	60,155	9,663	834
United Kingdom	67.9	83%	40	6,866,481	296,857	41,736	615
Spain	46.8	80%	45	4,826,516	291,189	27,136	580
Italy	60.5	69%	47	4,648,825	237,290	34,371	568
Sweden	10.1	88%	41	325,000	52,383	4,891	484
France	65.3	82%	42	1,384,633	157,372	29,436	451
United States	331.0	83%	38	25,268,136	2,183,598	118,339	358
Netherlands	17.1	92%	43	484,389	49,087	6,070	354
Ireland	4.9	63%	38	367,780	25,321	1,706	346
Switzerland	8.7	74%	43	465,722	31,146	1,939	224
Canada	37.7	81%	41	2,183,476	99,147	8,175	217
Brazil	212.5	88%	33	1,628,482	891,556	44,118	208
Mexico	128.6	84%	29	415,097	150,264	17,580	136
Iran	83.7	76%	32	1,293,609	192,439	9,065	108
Germany	83.8	76%	46	4,694,147	188,086	8,887	106
Denmark	5.8	88%	42	823,249	12,250	598	103
Austria	9.0	57%	44	532,700	17,189	681	76
Finland	5.5	86%	43	222,500	7,112	326	59
Turkey	84.3	76%	32	2,674,203	179,831	4,825	57
Russia	145.9	74%	40	15,395,417	545,458	7,284	50
Norway	5.4	83%	40	285,867	8,647	242	45
Israel	8.6	93%	30	772,074	19,338	302	33
Iceland	0.341	94%	38	63,198	1,812	10	29
Bahamas	0.393	86%	32	2,261	103	11	28
South Africa	59.3	67%	28	1,148,933	73,533	1,568	26
Egypt	102.3	43%	25	135,000	46,289	1,672	16
Pakistan	220.9	35%	23	922,665	148,921	2,839	13
Indonesia	273.5	56%	30	540,115	40,400	2,231	8
Bangladesh	164.7	39%	28	533,717	94,481	1,262	8
Japan	126.5	92%	48	340,918	17,502	925	7
India	1,380.0	35%	28	5,921,069	344,527	9,924	7
South Korea	51.3	80%	44	1,119,767	12,155	278	5
Australia	25.4	86%	38	1,844,126	7,347	102	4
China	1,439.3	61%	38	NA	83,221	4,634	3
Nigeria	206.1	52%	18	94,323	16,658	424	2
Hong Kong	7.5	100%	45	275,293	1,113	4	0.5
Ethiopia	115.0	21%	19	192,087	3,630	61	0.5
Total Worldwide	7,794.8	56%	31	90+ million	8,148,164	439,836	56

Source: Worldometer (June 16, 2020)