

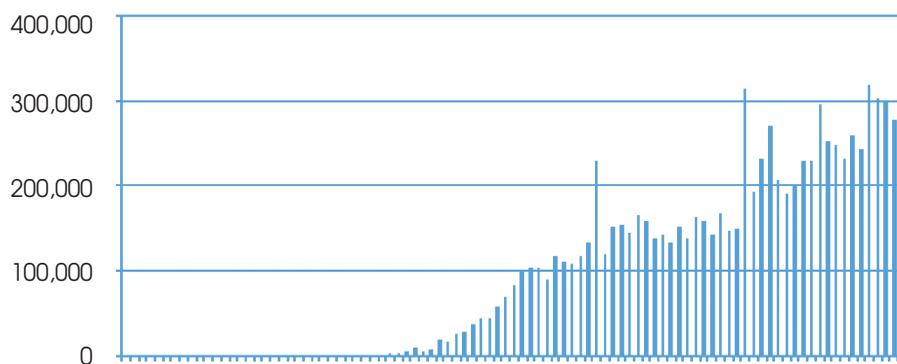
LABORATORY *E*CONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

Covid-19 Testing Ramp-Up Slowed By Supply Shortages

Supply shortages continue to prevent state public health labs, academic medical centers and commercial labs from reaching their full capacity to perform Covid-19 testing. U.S. labs performed an average of 273,000 Covid-19 tests per day during the first 10 days of May, according to the Covid Tracking Project, which gathers state testing data (*see graph*). That's an improvement from the last 10 days in April, when the U.S. averaged 222,000 tests per day, but still short of the 500,000 to 700,000 tests per day that Harvard Global Health Institute says is needed to begin reopening America.

Daily U.S. Covid-19 Test Volume (Feb. 7 to May 10, 2020)



Source: The Covid Tracking Project

Although supply lines are improving, most labs surveyed in late April/early May still reported difficulty in obtaining key components needed to perform Covid-19 testing. Fifty-eight percent of labs cited shortages of collection swabs and specimen transport media, according to *Laboratory Economics Covid-19 Survey of Labs*. Fifty-seven percent of labs also reported shortages in PPE (masks, gloves and gowns), while 47% of labs reported shortages in PCR-based Covid-19 test kits.

Is your lab experiencing a shortage in any of the following supplies?

- Collection swabs and/or specimen transport media.....58%
- Personal Protective Equipment (masks, gloves, gowns, et al.).....57%
- PCR-based Covid-19 test kits/reagents.....47%
- Covid-19 antibody test kits/reagents25%
- Routine test kits/reagents14%
- Hand sanitizer and/or surface cleaners.....3%

Source: *Laboratory Economics Covid-19 Survey of Labs* (April 22 – May 5, 2020; n=179)

For a complete summary of *Laboratory Economics Covid-19 Survey of Labs*, see pages 5-7.

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Spotlight Interview with Mayo Clinic Labs' President William Morice, MD, PhD

Mayo Clinic Laboratories, a global reference lab based in Rochester, Minnesota, typically performs about 25 million tests a year. *Laboratory Economics* recently spoke with President William Morice, MD, PhD, about the impact Covid-19 is having on the laboratory.



*William Morice,
MD, PhD*

What happened to Mayo Clinic Laboratories' test volume after mid-March?

Our overall test volumes have decreased. We really hit the nadir in late-March and volumes were stably reduced through mid-April. At our low point volumes were reduced approximately 30%, but we are now rebounding. It's indicative that we are opening up healthcare more. Not all volumes dropped in the same way. Some of our testing didn't drop as much as we anticipated, particularly around oncology testing, which makes sense as this is a vital medical service.

When did Mayo begin PCR-based Covid-19 testing and which analyzer system is used?

We began developing our own LDT in early February, and we went live in early March (we received an emergency use authorization). We also had Roche 6800 analyzers here. We were able to obtain an additional one for Rochester and one for Mayo Clinic in Florida. So, we are predominantly using the Roche platform, but we are also using Abbott and Cepheid. We're running our EUA approved Mayo developed test in the molecular virology lab and are primarily using this assay for our patients being served by the Mayo Clinic practice.

What is your approximate volume from PCR-based Covid-19 testing?

Currently, we are running approximately 7,000 to 7,500 molecular Covid-19 tests daily for our Mayo Clinic Laboratories customers. In addition, we are running approximately 2,000 to 2,500 molecular Covid-19 tests per day for our Mayo Clinic patients and providers.

Are you increasing your capacity? If so, by how much?

Yes, we continue to increase our capacity both in Florida and in Rochester in large part to continued growing demand. Mayo Clinic Laboratories, along with the University of Minnesota, is a key partner in the state's moon shot for Covid-19. The goal is to get to 20,000 PCR tests and 15,000 serologic tests per day in Minnesota. I believe Florida is still formulating its plan.

As Mayo Clinic looks to re-open its practice and start doing outpatient procedures, we clearly will have to increase capacity to test patients and providers for Covid-19. We turn around most tests within 24 hours.

When did Mayo begin Covid-19 antibody testing and which test vendor is used?

We went live in the first week of April. We are using Euroimmun, but as with all Covid-19 testing, the supply chain can be uncertain, so we are continuing to look at other alternatives.

What is your approximate volume from Covid-19 antibody testing?

Currently we are running approximately 2,500 to 3,000 serologic tests per day.

Describe the difficulties in getting supplies, such as swabs, test kits, reagents.

Everyone in the industry has had challenges with the supply chain. For us, a lot of the challenges were around swabs. We also had challenges with our platforms. Roche has been good, but the machines are complex, and sometimes it has been hard to get access to the parts and

personnel to fix them when they go down. Our LDT RNA extraction equipment is produced in Italy, and early on we had some problem getting that. We monitor the supply chain daily. We have designed our processes so we can move between platforms when needed. This pandemic and the overwhelming need for testing will continue to put pressure on the supply chain.

Are you starting to see non-COVID testing increase?

Yes, we are. We have seen testing rebounding. We have seen some fluctuation in volumes early, as well as some odd spikes in demand for different tests, such as G-6-PD testing related to the use of hydroxychloroquine. We are watching on a week by week basis, but we do expect volumes to continue to increase.

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

Yes, we had to reforecast, but it's too early to tell by how much. We think we will come back to normal volumes in a couple of months. A lot will depend on the economic recovery, which is hard to get a handle on.

What do you believe the long-term effect of COVID will be on Mayo?

As a whole, the ramifications will be around how we deliver care. There will be an increasing demand for remote care. On any day now at Mayo Clinic, we perform more remote patient care visits than we did in all of 2019. We'll also start to see a much greater demand for either at-home testing or remote testing. It will change where the patients expect to have their labs drawn and when providers expect to have results in relation to the patient visit.

Spotlight Interview With Wisconsin Diagnostic Labs' CEO Steve Serota

Wisconsin Diagnostic Laboratories (Milwaukee) has experienced double-digit volume growth in each of the past three years, partly due to an expansion in outreach testing. While Covid-19 has temporarily depressed test volumes, CEO Steve Serota predicts that volumes will recover. *Laboratory Economics* recently spoke with Serota about the impact Covid-19 is having on the lab.



Steve Serota

What happened to WDL test volume after mid-March?

As the virus started to ramp up and proliferate across central Wisconsin, we saw a pretty dramatic fall-off of our testing volumes. As hospital volumes started to wane, we saw a drop of about 45% for March and into early April.

What does that drop in volume mean for WDL?

For us, it meant making sure we have a strong operational infrastructure in place. We were in the process of rebuilding our lab's whole-line automation, so we were able to redirect some resources to build a Covid testing platform that met the needs of our partners and the communities we served.

When did WDL begin PCR-based Covid-19 testing and which analyzer system is used?

We actually are on a myriad of different platforms. We started on [BioMerieux's NUCLISENS] eMag on March 24. Our micro/molecular team built out our lab-developed test using CDC guidelines, and we received emergency authorization approval from FDA. The full process was completed in seven days. We also have the Roche cobas 6800 unit, so we were able to start running the Roche tests on that once reagents became available. We partnered with Cepheid and went live on their GeneXpert with a rapid 45-minute turnaround assay. To boost our capacity

further, we brought in Thermo Fisher's KingFisher system with a PCR back-end. The development of this multimodality approach has been essential for the durability of our supply chain.

What is your approximate volume from PCR-based Covid-19 testing?

We were seeing an average daily volume in the 1,000 per day range, but it is ramping up. We have internal testing capacity of about 1,500 tests a day, but we don't have the demand yet. We are starting to see criteria for who should be tested loosening up, so we expect those numbers to go up. We think 1,400 tests per day will be the new normal for May. We expect to see the demand for PCR testing to remain strong. One thing I am most proud of is WDL's turnaround time, which never exceeded seven hours, even for our outreach clients.

When did WDL begin Covid-19 antibody testing and which test vendor is used?

We are in the process of bringing that up right now. We have validated a few different tests – the Euroimmun's ELISA test, Abbott's serology test on the Alinity instrument and Roche's total antibody test. We will begin running antibody tests this week with capacity to perform over 10,000 tests per day.

Describe your difficulties in getting supplies, such as swabs, test kits, reagents.

We were able to secure early access to supplies, but the problems with the supply chain soon became apparent, which is why we took a multi-modality approach. We had the core infrastructure but not the supplies. For example, the Roche 6800 can run 1,200 samples a day, but we were not initially able to receive that as a daily allocation. Certain vendors have been able to catch up, and the diversity of tests available has lessened the burden, but there are still areas of challenge. The biggest challenge is availability of rapid tests.

Are you starting to see non-COVID testing increase?

We have seen an uptick of about 24% in the past few days, and we expect that to increase daily. I expect to get back to volumes prior to Covid in the next two months but with a different mix. I think AP volumes will come back quickly—we have seen a 40% bump to date.

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

We have. We're on a July fiscal year, so this hit us in the end of the third, beginning of fourth quarter. We have done a phenomenal job of appropriately right-sizing to meet the demand. We are projecting an overall revenue drop of 6% to 8%.

What do you believe the long-term effect of COVID will be on WDL?

I think the Covid-19 pandemic has allowed us the opportunity to shine a light on the value of community laboratory services. WDL has been able to provide less than seven-hour turnaround time to our patients from day one. As a result, more informed clinical decisions have been made. This rapid access to patient status has allowed our partners to preserve scarce resources like PPE and isolations rooms. In addition, it has allowed our patients peace of mind and the ability to make informed decisions for themselves and their families.

The mission of WDL has always been to safe guard and improve the health of the communities we serve and this pandemic has illuminated the true value of timely and appropriate community access to industry leading laboratory medicine.

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Laboratory Economics Covid-19 Survey of Labs

The *Laboratory Economics Covid-19 Survey of Labs* was emailed to approximately 6,000 pathologists, laboratory directors, managers and executives between April 22 and May 5. We received complete responses from 179 individuals, including 35% from local independent pathology groups/labs, 22% from hospital-based pathology groups, 17% from national pathology/commercial lab companies, 12% from academic medical centers, and 6% each from hospital-based outreach labs and physician office labs.

Survey Respondents by Laboratory Type

Local independent pathology group/lab	35%
Hospital-based pathology group.....	22%
National pathology/commercial lab.....	17%
Academic Medical Center	12%
Hospital-based outreach lab	6%
Physician office lab	6%
Other lab	2%

Source: *Laboratory Economics Covid-19 Survey of Labs*

PCR-Based Covid-19 Testing

Fifty-five percent of survey respondents said their lab currently performs PCR-based Covid-19 testing. Another 12% said they were planning to add PCR-based Covid-19 testing.

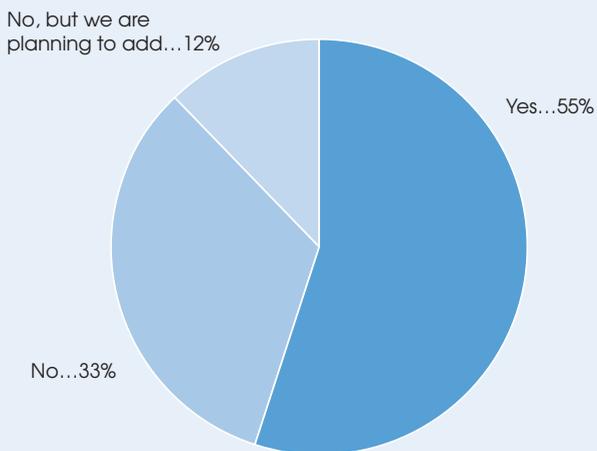
“We currently have Abbott ID NOW on line with limited capacity. We also have Cepheid GeneXpert and BioFire platforms but are unable to obtain test kits,” according to a hospital lab in California.

“We should have had the test implemented by now if it weren’t for lack of necessary reagents and supplies,” said a pathologist in California.

“We are unable to source Covid-19 tests at this time,” according to an independent lab in Iowa.

“Everything is in short supply. We have moved outside of traditional distributors and gone straight to factories and manufacturers both domestic and international. We will be better off after this crisis when we will not be held hostage by the distributors any longer,” according to an independent lab in North Carolina.

Does your lab currently perform PCR-based Covid-19 testing?



Source: *Laboratory Economics Covid-19 Survey of Labs*

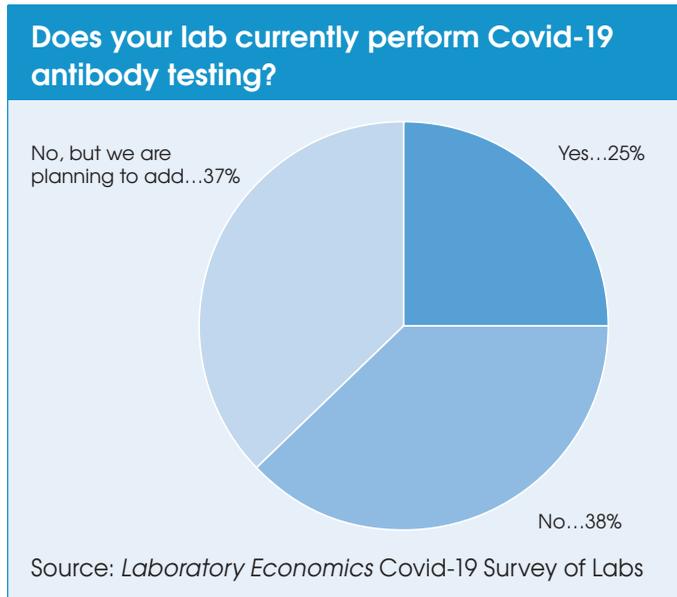
“The country wants mass testing to open up the economy, but we are struggling greatly to get test kits and collection supplies. The vendors are struggling and they are reporting they will have their production ramped up in early May,” according to a pathology lab from Washington.

“Our supply chain is gradually opening up, in large part because we have brought numerous commercial platforms up for both PCR and antibody testing. But it has been a long and difficult ‘supply chain’ journey. Nasopharyngeal swabs and universal transport media also have been

a bottleneck, but we have made disciplined use of PCR testing which has helped NP Swabs/UTM supplies keep pace,” said a pathologist from New York.

Covid-19 Antibody Testing

Twenty-five percent of survey respondents said their lab currently performs Covid-19 antibody testing. Another 37% said they were planning to add Covid-19 antibody testing with many indicating that they'll be going live with testing in May.



“We’re currently sending out to Quest, but will be adding the Ortho antibody test on our 5600’s in mid-May,” according to a hospital lab in Wisconsin.

“We will outsource to Mayo clinic labs until reagents become available for our instruments in a few weeks,” according to an independent lab in New Mexico.

Routine Test Volume Trends

Nearly all surveyed labs (93.1%) said their overall volume had declined since mid-March, including 42.9% that cited volume declines of more than 50%.

Only 4.5% of all surveyed labs reported their volume had increased.

“Physician offices are closed. It’s as simple as that,” noted an independent lab in New Mexico.

“The slow-down at hospitals, surgery centers and physician offices plus the elimination of elective surgery has crushed our volume in excess of 50%; down as much as 70% to 90% depending on the day,” according to pathology lab in California.

“Inpatient testing is up 100%, while outreach is down 75%,” according to a hospital lab in Connecticut.

“Surgical pathology volume is down greater than 80%,” reported a pathologist from New Jersey.

Physician office-based labs and independent anatomic pathology groups have been the hardest hit categories. Nearly 67% of surveyed POLs reported seeing their volume cut by more than 50% since mid-March, while 64% of local independent pathology groups/labs reported 50%+ volume declines.

Has your lab experienced an overall decline in test volume since mid-March?

Our test volume has increased.....	4.5%
Our test volume is steady	1.7%
Test volume down -1% to -10%.....	5.6%
Test volume down -11 to -30%.....	13.0%
Test volume down -31% to -50%	31.6%
Test volume down more than 50%.....	42.9%

Source: Laboratory Economics Covid-19 Survey of Labs

Type of lab reporting a test volume decline of more than 50%

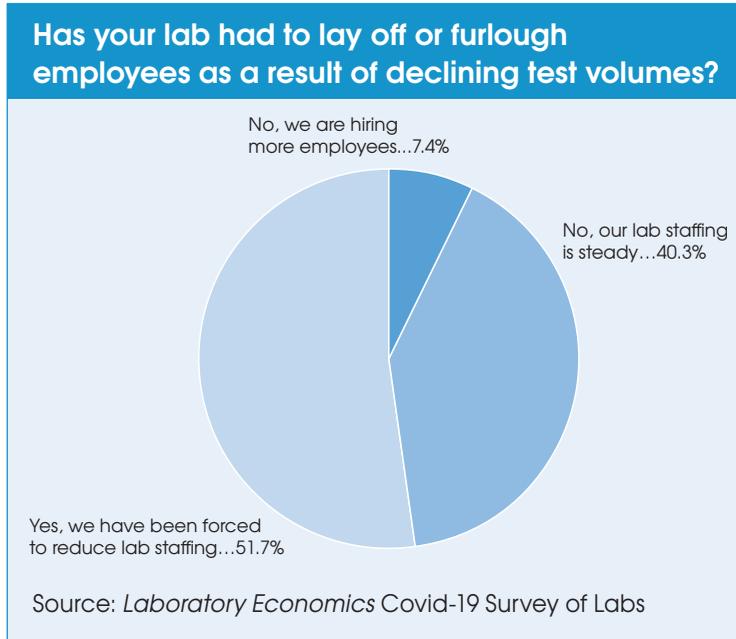
Physician office lab.....	66.6%
Local independent pathology group/lab	64.4%
Hospital-based outreach lab	50.0%
National pathology/commercial lab.....	44.8%
Hospital-based pathology group.....	21.2%
Academic Medical Center	19.0%

Source: Laboratory Economics Covid-19 Survey of Labs

Lab Staffing Reductions

Nearly 52% of surveyed labs said they had been forced to lay off or furlough employees as a result of declining test volumes. Only 7.4% of surveyed labs said they were hiring more employees.

“We have frozen the recruitment of replacing four vacated positions. We also have one more employee who will be retired at the end of May. In total, we will freeze all five replacements to save money until the volume of tests rebound,” according to an academic medical center in New York.



“We received a PPP loan that required us to retain our current level of staffing. However, if testing does not pick up at the end of our loan/grant term, we will be forced to furlough staff,” said an independent lab from Iowa.

“We have split the lab into two teams. Each works two weeks then takes two weeks off,” according to an independent pathology lab in Kentucky.

“We have allowed all non-lab employees to work from home and have staggered lab shifts to minimize the risk to our employees. Our volume is down nearly 70%, but we chose not to reduce staffing and will focus on

Covid testing,” according to an independent pathology lab in New Jersey.

Nearly 67% of surveyed POLs reported that they had reduced staffing, while only 20% of hospital-based outreach labs reported cutbacks.

Final Survey Comments

Participants were asked for their general opinions on the Covid-19 crisis. Selected comments are provided below.

“Never before has a country closed and quarantined healthy people. The sick and susceptible to the disease should for sure be quarantined, but not healthy individuals. This went way too far,” according to an independent lab in Florida.

“As long as we see reimbursement, we will survive. If payments for Covid-19 testing are delayed or lower than \$100, we will likely have to lay off employees and/or go out of business,” said an independent lab in Georgia.

“Just in time ordering will not work anymore and we will plan differently in the future. I would have thought by now, swab supply would not be an issue,” noted a hospital lab in Wisconsin.

Type of lab that has reduced staffing

Physician office lab.....	66.6%
National pathology/commercial lab.....	55.1%
Local independent pathology group/lab	54.2%
Academic Medical Center	52.3%
Hospital-based pathology group.....	48.4%
Hospital-based outreach lab	20.0%

Source: Laboratory Economics Covid-19 Survey of Labs

Quest Diagnostics Reports First-Quarter Results

Quest Diagnostics reported net income of \$99 million for the three months ended March 31, 2020, down 40% from \$164 million in the same period a year ago; revenue was down 3.7% to \$1.822 billion. A summary of key topics discussed by CEO Steve Rusckowski and CFO Mark Guinan on an April 22 conference call follows.

Overall Volume

Overall test volume is currently down 50% to 60% from a year ago. This figure includes the added volume from PCR-based Covid-19 testing. Quest is currently performing an average of 50,000 PCR-based Covid-19 tests per day using three different molecular test platforms (Quest LDT, Roche and Hologic) at 12 Quest labs. Its highest volume PCR-based Covid-19 testing labs are located at San Juan Capistrano, CA, Chantilly, VA, and Marlborough, MA. Rusckowski said that Quest was planning to further increase its volume of PCR-based Covid-19 testing. “It’s very dependent upon IVD manufacturers providing us with the reagents and the kits to be able to increase our capacity...we’re hopeful we can build on what we have, but we are rate-limited by that.”

Covid-19 Antibody Testing

Quest began Covid-19 antibody testing on the Euroimmun/PerkinElmer platform in mid-April and then added Abbott’s antibody test. Quest expects to scale up its Covid-19 antibody testing volume from approximately 70,000 tests per day at the end of April to approximately 200,000 tests per day by mid-May. Quest is also pursuing other platforms that could further increase its testing volume. Once again, Rusckowski said that the limiting factor was not Quest’s lab capacity, but its ability to get reagents from IVD manufacturers.

Employee Cutbacks

Quest has taken several temporary actions to manage its workforce costs and conserve cash to offset volume declines related to the pandemic. Rusckowski has taken a 25% pay cut and salaried employee pay has been reduced by 20% for the most senior executives to 5% depending on level. These pay reductions will be in place for 12 weeks. Quest has also furloughed more than 5,500 employees, or approximately 12% of its workforce, reduced overtime, frozen virtually all hiring and promotions and dismissed temporary and contract workers. “We want to maintain flexibility because we know when the crisis ends, our volumes will begin to recover, and we’ll need our colleagues more than ever,” said Rusckowski.

The CARES Act

The Coronavirus Aid, Relief, and Economic Security (CARES) Act, which became law in late March, set aside \$100 billion to healthcare providers for expenses or lost revenues attributed to Covid-19. Quest received approximately \$65 million from the initial tranche of the \$30 billion distributed to providers in early April.

PAMA

“This crisis has brought to the forefront the importance of testing. And I never believed when I joined this company over eight years ago, that labs would be on the front page of every newspaper in America and all over the media. So it’s much easier now for us to make our case with members of Congress and the administration in HHS with the value of testing and the need for us to get fairly reimbursed and also to reinforce the intent of Congress and making sure we get a new [PAMA] process put in place that properly reflects the market rates,” said Rusckowski.

Acquisitions

On January 21, Quest completed its acquisition of the Finnish genetic testing company Blueprint Genetics for \$108 million in cash. On April 6, Quest completed its purchase of Memorial Hermann Diagnostic Laboratories (Houston, TX), the outreach laboratory division of Memorial Hermann, for \$120 million in cash. Rusckowski said that Quest had other transactions in the pipeline that it was close to finalizing before the crisis, but are now on hold.

LabCorp Reports First-Quarter Results

LabCorp reported a net loss of \$317.2 million for the three months ended March 31, 2020, down from net income of \$185.6 million in the same period a year ago; revenue was up 1.2% to \$2.824 billion. A summary of key topics discussed by CEO Adam Schechter and CFO Glenn Eisenberg on an April 29 conference call follows.

Diagnosics Division

LabCorp's Diagnostics Division reported a 1.2% decline in revenue to \$1.702 billion. Volume decreased by 4.4%, including an organic volume decrease of 6.1%, partially offset by acquisition volume of 1.6%. LabCorp's requisition volume is currently down by roughly 50% to 55% versus the company's normal pre-Covid-19 crisis volumes.

Increased demand for Covid-19 testing is marginally offsetting the loss in routine test volumes, according to Schechter. He said that LabCorp is currently able to perform more than 60,000 PCR-based Covid-19 tests per day, or 1.8 million per month, and is seeking to expand to over 100,000 tests per day.

LabCorp's primary PCR-based Covid-19 testing locations are Burlington, NC; Indianapolis, IN; Phoenix, AZ; and Raritan, NJ. LabCorp is performing the majority of its testing on analyzers from Thermo Fisher and Roche, in addition to the Hologic Panther Fusion System. "The issue that you run into is you need additional machines and you can imagine there's lots of back orders and you know doing these RNA tests and the PCR test takes a lot of equipment. But we're going to try to build to get to over 100,000 as quickly as we can," said Schechter.

Home Sample Collection Kits

LabCorp launched its Covid-19 at-home self-collection kits through its branded Pixel service in late April. The kits allow patients to swab their own nasal passages and mail the samples back to LabCorp for PCR-based Covid-19 testing. The service is currently available only for healthcare workers and first responders who have Covid-19 symptoms. To obtain a collection kit, an individual must first fill out an online questionnaire, which is then reviewed and authorized by a physician. LabCorp will bill private insurance or utilize federal funds to cover the upfront cost of the test, while self-paying customers pay \$119. LabCorp intends to make the collection kits available to all consumers in the coming weeks. However, the service is not available in MD, NJ, NY, and RI, due to state restrictions.

Covid-19 Antibody Testing

LabCorp can currently perform more than 50,000 Covid-19 antibody tests per day and expects to increase its capacity to over 200,000 tests per day by mid-May. LabCorp is using Abbott's antibody test. "When you think about those numbers, over 200,000 tests today in serology and maybe 100,000 tests over time for PCR, it's still a very small number compared to the 530 million or so tests that we do across all of our testing [pre-Covid-19]. So unless we start to see that come back, it will be hard for these tests to make up for the difference in what we've seen since the last weeks of March," according to Schechter.

Accounts Receivable

LabCorp said that, as a result of increase in unemployment and the potential financial difficulties of medical practices from the impact of the Covid-19 crisis, it took a first-quarter charge of \$17 million to increase its accounts receivable reserves.

Cost Cutting

Some of the actions that LabCorp has taken to help offset the impact of Covid-19 include employee furloughs, delays in new hiring, reducing temporary and contract workers, and suspension of merit pay hikes and 401(k) plan contributions.

The CARES Act

LabCorp received \$56 million in April through the CARES Act, which the company is using to ramp up its Covid-19 testing capacity.

Spotlight Interview With NMG's David Nichols

Pacific Diagnostic Laboratories (PDL-Santa Barbara, CA) is a full-service clinical and anatomic laboratory owned by Santa Barbara Cottage Hospital, an affiliate of Cottage Health. Since being formed in 2007, PDL has contracted with Nichols Management Group (NMG-York Harbor, ME) for management services. Below NMG President David Nichols provides an update on PDL.



David Nichols

Would you describe Pacific Diagnostic Laboratories?

PDL has 300 employees and operates a freestanding offsite laboratory in Santa Barbara and 25 PSCs throughout the central California coast. PDL serves more than 500,000 outreach patients per year and also manages the inpatient labs for three Cottage Health System hospitals: Santa Barbara Cottage Hospital (519 beds), Goleta Valley Cottage Hospital (28 beds) and Santa Ynez Valley Cottage Hospital (11 beds).

When did PDL begin PCR-based Covid-19 testing?

PDL began semi-automated testing using the GenMark Diagnostics platform in late March. PDL added Becton Dickinson's BD Max and Abbott's ID Now system in April. PDL is using three different vendors in order to maximize its supply line. Combined PDL is currently performing an average of 250 PCR-based Covid-19 tests per day, primarily for inpatients and frontline healthcare staff. PDL is expected to increase its testing capacity soon. Other testing in the community is referred by the Santa Barbara County Health Department with whom PDL has a close relationship to support community health. Currently, PDL is referring its overflow non-inpatient specimens to LabCorp and Sonic Healthcare.

What are your plans for Covid-19 antibody testing?

Right now, PDL is referring its Covid-19 antibody testing to LabCorp. But we'll be bringing antibody testing inhouse by the end of the month.

Is PDL experiencing any supply shortages?

Just as most labs across the country, we're seeing across-the-board shortages for PPE, swab collection kits and test reagents. Our buyers and managers are spending a lot of time hunting down supplies. And we see in real-time the competition between the federal government, state and local governments and national and local labs for limited supplies. We're hoping the supply chain gets straightened out soon because we expect a new wave of demand for Covid-19 testing to start when patients start going to doctors' offices again.

What has happened to PDL's non-Covid-related test volumes?

Over the past few years, PDL had consistently grown its test volume by 5% to 10% per year. However, after the statewide lockdown in mid-March, overall test volume at PDL fell by roughly 50% to 55%. Since the start of May we've begun to see a significant rebound in test volumes.

Has PDL reduced staff in response to volume declines?

PDL has remained fully staffed to serve our patients.

How will coronavirus change the lab industry over the next two or three years?

The pandemic has highlighted the importance of lab testing and raised the value of lab departments at health systems. Hospitals may be less inclined to outsource their lab in the future.

Depressed volumes have added to the pressure that independent clinical labs were already facing after three straight years of PAMA rate cuts. The pace of consolidation will accelerate.

In addition, Covid-19 may be a key catalyst in the nascent direct-to-consumer laboratory testing market. The national labs are taking advantage of consumer demand and subsequent lab branding opportunities.

Covid-19 Situation Update At Five Laboratories

Last month, *Laboratory Economics* highlighted five different laboratories and their response to the Covid-19 crisis. Below we provide a quick update on each of those labs.

Viracor Eurofins Laboratories

Viracor Eurofins Laboratories (Lee's Summit, MO) has the capacity to perform 2,000 PCR-based Covid-19 tests per day; however, about 50% of that capacity is currently unused, according to Steven Kleiboeker, PhD, Vice President of Research and Development. Nationwide, Eurofins U.S. Clinical Diagnostics, which includes Viracor and six other laboratories, has the capacity to run up to 10,000 PCR tests per day and expects to triple that number by the end of this month.

Viracor launched Covid-19 antibody testing on May 5 and has the capacity to perform more than 2,000 tests per day with a 24-hour turnaround from specimen receipt. Nationwide, Kleiboeker says that Eurofins' seven labs can currently perform up to 10,000 antibody tests per day with capacity expected to triple by the end of this month.

Kleiboeker expects the demand for Covid-19 testing to increase dramatically as lockdowns in many states have begun to be lifted. That being said, Eurofins currently has excess testing capacity. "This is due to a variety of factors, including hospitals taking their testing in-house, supply-chain issues, and on the coasts, exclusive deals between the top insurance companies and the two largest labs," according to Kleiboeker.

ARUP Laboratories

ARUP Labs is currently performing between 3,000 and 3,500 PCR-based Covid-19 tests per day and steadily increasing its capacity, according to Julio Delgado, MD, Chief Medical Officer and Director of Labs. He says that the swab and test kit supply situation has improved over the past few weeks and that ARUP has expanded its Covid-19 testing from Utah patients only to nationwide. In addition, ARUP began Covid-19 antibody testing in late April and is now performing about 5,000 antibody tests per day with steadily increasing capacity.

Northwell Health Labs

Northwell is currently performing about 2,000 PCR-based Covid-19 tests per day, according to James Crawford, MD, PhD, Senior Vice President for Laboratory Services. He says daily positivity rates for Covid testing peaked at 63% on March 31 and have now fallen to roughly 15%. In response to shortages, Northwell has begun using its own self-manufactured 3D swabs, which were clinically validated before deploying. In addition, Northwell started performing antibody testing on May 1 using multiple commercial platforms. Northwell is currently performing about 5,000 antibody tests per day and is in the process of testing its 70,000 employees.

American Health Associates

American Health Associates (Davie, FL), which provides lab testing services to more than 4,000 nursing homes and assisted-living facilities, recently began performing PCR-based Covid-19 testing and serum antibody testing at its corporate laboratory near Miami. Previously, AHA had sent its Covid-19 test samples to LabCorp. AHA is using the 7500 Fast Dx instrument from Thermo Fisher Scientific in combination with Thermo's 96 Kingfisher auto extraction unit for PCR-based Covid-19 testing. AHA will be using Abbott's Covid-19 antibody test. In addition, AHA plans to soon add Covid-19 testing capabilities to its labs in Atlanta and Cincinnati, according to CEO Chris Martin. AHA is currently performing an average of roughly 100 PCR-based Covid-19 tests per day and 350 antibody tests. Martin expects AHA's Covid-19 testing volume to expand rapidly in the coming weeks.

BioReference Labs

To date (through May 6), BioReference has performed approximately 700,000 PCR-based Covid-19 tests, is currently performing about 20,000 tests per day, and plans to reach 40,000 by the end of the month. In late April, BioReference started offering Covid-19 antibody testing. Capacity is currently 20,000 tests per day and is expected to reach 400,000 tests per day in June, according to Jon Cohen, MD, Executive Chairman of BioReference Labs. Roche will be the primary antibody assay used by BioReference.

Lab Stocks Up 9% Year To Date

Twenty lab stocks have risen by an unweighted average of 9% year to date through May 8. In comparison, the S&P 500 Index is down 9.3% so far this year. The top-performing lab stocks thus far in 2020 are Vermillion, up 157%, and Opko Health, up 43%. Shares of LabCorp are down 1%, while Quest Diagnostics is up 5%.

Company (ticker)	Stock Price 5/8/20	Stock Price 12/31/19	2020 Price Change	Enterprise Value (\$ mill)	Enterp Value/ Revenue	Enterp Value/ EBITDA
LabCorp (LH)	\$167.26	\$169.17	-1%	\$22,350	1.9	16.6
Quest Diagnostics (DGX)	112.22	106.79	5%	18,610	2.4	12.5
Sonic Healthcare (SHL.AX)*	25.90	28.75	-10%	16,070	2.5	12.3
Exact Sciences (EXAS)	82.01	92.48	-11%	12,840	14.7	NA
Guardant Health (GH)	88.15	78.14	13%	7,160	33.4	NA
Natera (NTRA)	43.57	33.69	29%	3,160	9.6	NA
NeoGenomics (NEO)	28.10	29.25	-4%	3,130	7.5	86.8
Invitae (NVTX)	17.16	16.13	6%	1,720	7.2	NA
Opko Health (OPK)	2.10	1.47	43%	1,590	1.8	NA
CareDx (CDNA)	28.25	21.57	31%	1,230	8.8	NA
Veracyte (VCTY)	28.11	27.92	1%	1,220	10.0	NA
Myriad Genetics (MYGN)	14.62	27.23	-46%	1,220	1.6	NA
Castle Biosciences (CSTL)	31.50	34.37	-8%	422	8.1	41.0
Vermillion Inc. (VRML)	2.08	0.81	157%	189	41.7	NA
DermTech Inc. (DMTK)	13.83	12.40	12%	189	56.1	NA
Exagen (XGN)	15.73	25.40	-38%	141	3.5	NA
Enzo Biochem (ENZ)	2.82	2.63	7%	101	1.3	NA
Biocept (BIOC)	0.41	0.29	42%	43	7.8	NA
Psychemedics (PMD)	5.60	9.15	-39%	30	0.8	5.1
Interpace Biosciences (IDXG)	5.07	5.00	1%	19	0.8	NA
Unweighted Averages			9%	\$91,433	11.1	29.1

*Sonic Healthcare's figures are in Australian dollars

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

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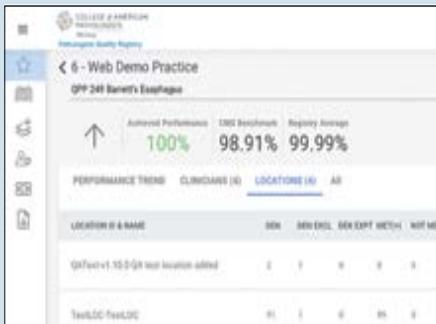
NOTHING'S BETTER THAN A CUSTOM FIT

Reduce MIPS Reporting Burdens and Maximize Performance with Practice-Specific Support

Complimentary Advisory Services

Successfully navigating the complexities associated with the Centers for Medicare and Medicaid Services' (CMS) Merit-based Incentive Payment System (MIPS) places a burden on pathology practices. It is critical to report the data that uniquely highlights your pathology practice's value in the MIPS program.

MIPS experts at the College of American Pathologists (CAP) are available to help you select the measures that best fit your practice, demonstrate your value, and optimize your payment potential.



QCDR: A Holistic Approach to MIPS Reporting

A Qualified Clinical Data Registry (QCDR) collects medical or clinical data for the purpose of patient and disease tracking to foster improvement in the quality of care provided.

A CMS-approved QCDR can include meaningful, applicable, and unique specialty-specific (QCDR) quality measures—as well as options to consolidate reporting across required MIPS categories, and opportunities to benchmark performance.

Flexibility for Reduction of Administrative Burden

A registry can collect your data from a variety of sources such as claims data, laboratory information systems, and other quality-reporting systems—and submit it to CMS on your behalf.

The Pathologists Quality Registry is a QCDR that offers your practice tailored submission mechanisms to reduce reporting burdens and quality measures to maximize your MIPS potential. Through the Registry, you can:

- Report as an individual or as a group
- Use the web-interface option for manual case entry
- Download templates for data collection in your practice
- Bulk upload data to the Registry
- Automate data extraction from your LIS or billing company to further simplify data collection



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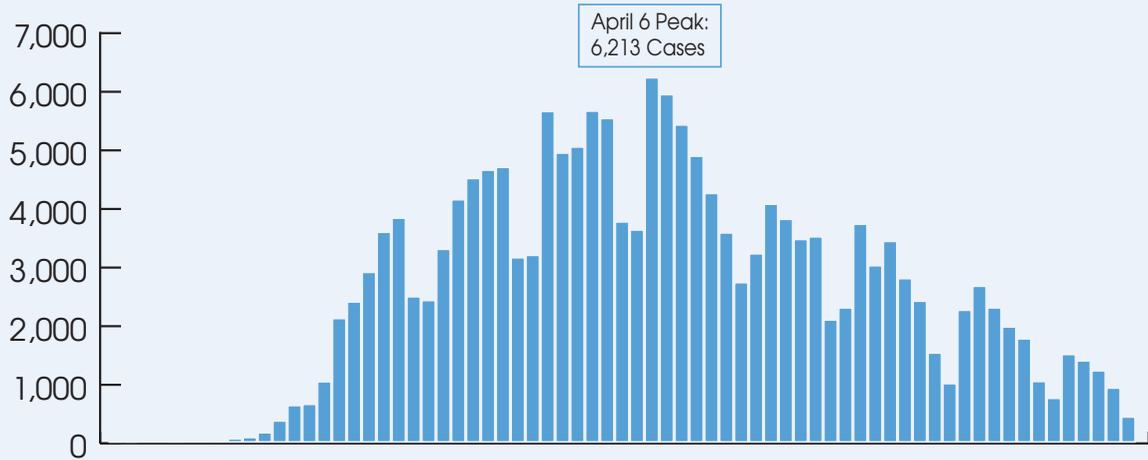
Learn how your practice might benefit from practice-specific support for complying with MIPS.

Contact our MIPS experts at mips@cap.org

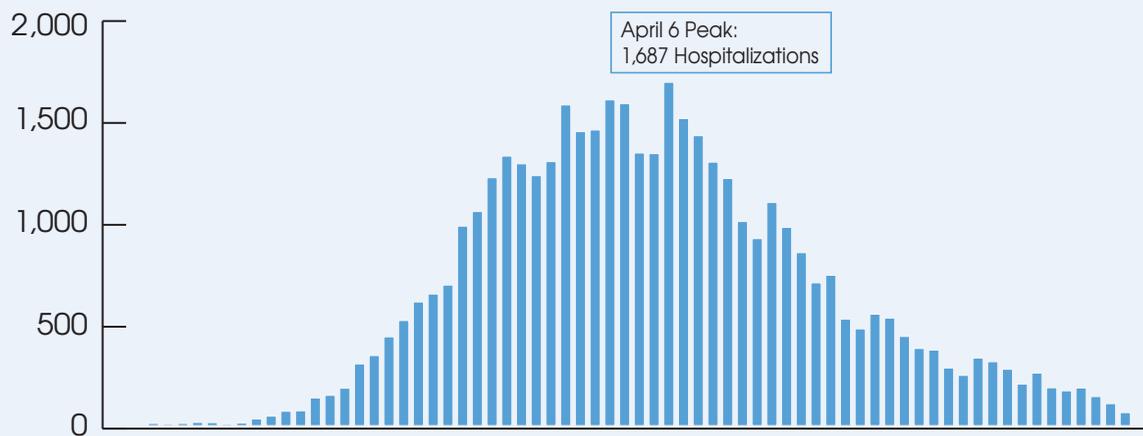
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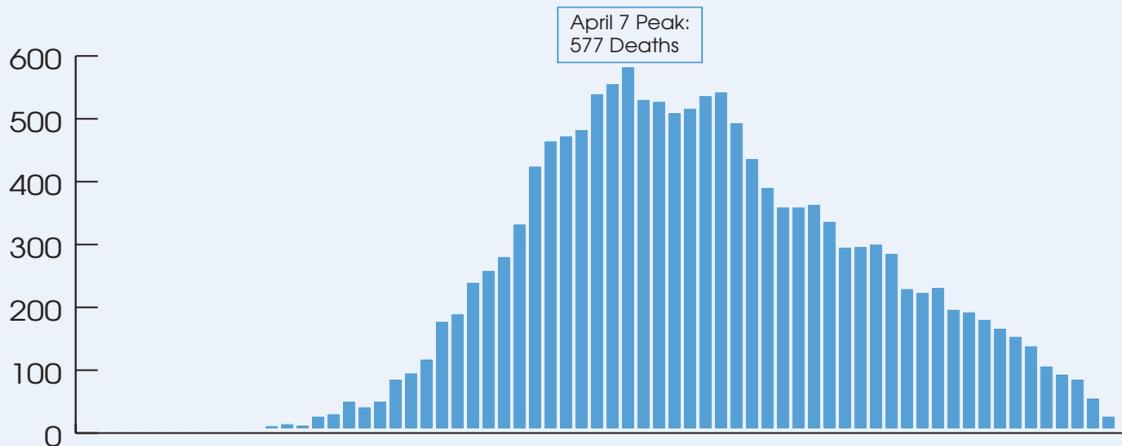
New York City Daily New Cases of Covid-19 (March 2 through May 8, 2020)



New York City Daily New Hospitalizations from Covid-19 (March 2 through May 8, 2020)



New York City Daily Deaths from Covid-19 (March 2 through May 8, 2020)



Source: NYC Department of Health and Mental Hygiene

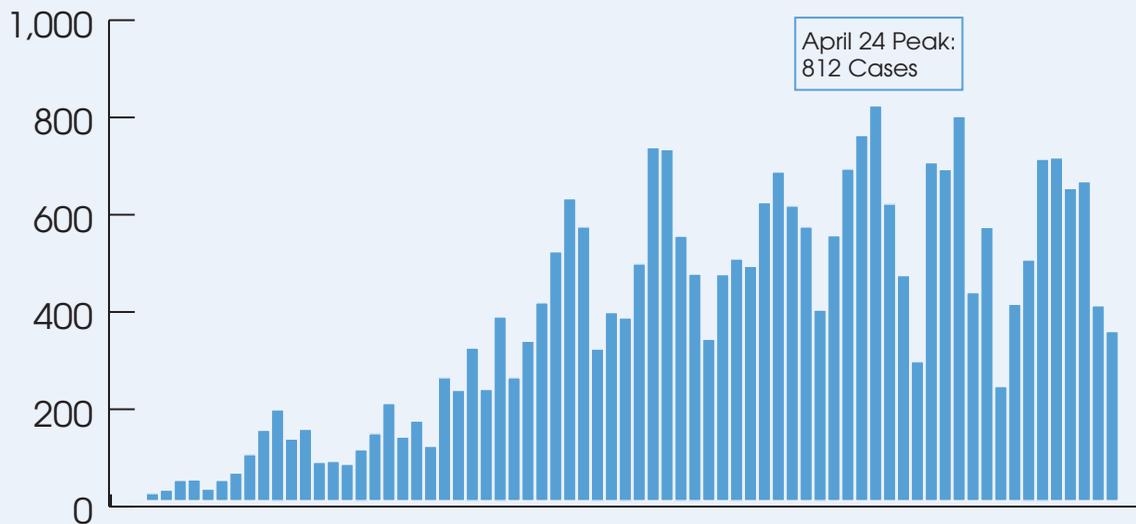
Sweden Approaching Herd Immunity

Sweden’s Chief Epidemiologist Anders Tegnell, MD, PhD estimates that 40% of people in the capital, Stockholm (total population: 974,000), will be immune to Covid-19 by the end of May, giving the country an advantage against a virus that “we’re going to have to live with for a very long time.” “In the autumn there will be a second wave. Sweden will have a high level of immunity and the number of cases will probably be quite low,” Tegnell told the *Financial Times* (April 28).

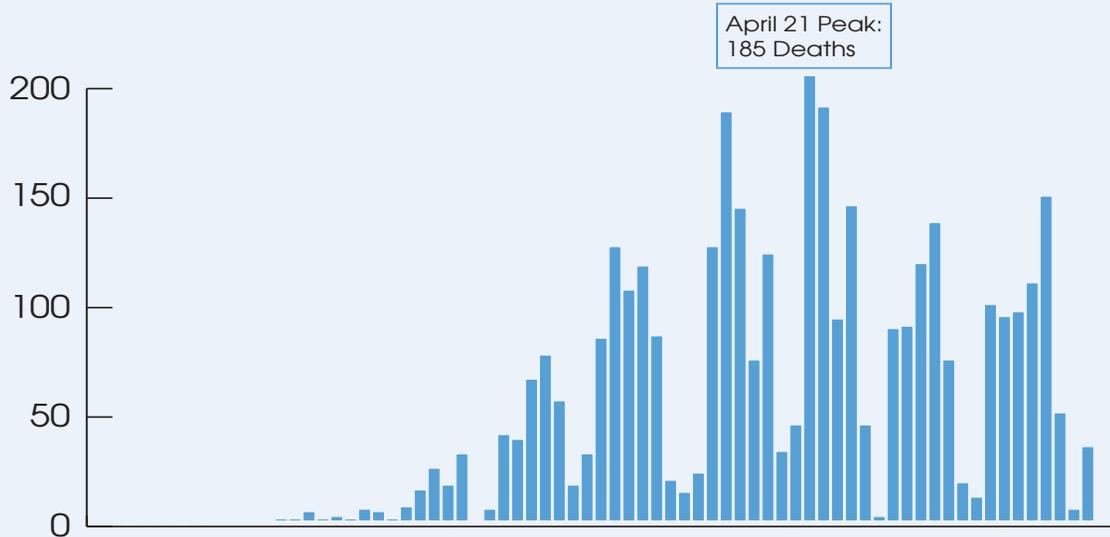
Overall, as of May 11, Sweden had 26,670 Covid-19 cases and 3,256 deaths—88% of fatalities have been people age 70 or older. The Covid-19 outbreak appears to have peaked in Sweden in late April. Sweden’s hospital system never reached more than 90% capacity, despite not instituting a “lock-down” strategy like most other nations.

Tegnell said it would take about one to two years to know whose strategy had worked best and at what cost to society.

Sweden’s Daily New Cases of Covid-19 (March 2 through May 11, 2020)



Sweden’s Daily Deaths from Covid-19 (March 2 through May 11, 2020)



Source: Worldometer and www.folkhalsomyndigheten.se

Covid-19 Statistics for Select Countries (May 11, 2020)

Country	Population (millions)	Urban Pop %	Median Age	Total Tests	Total Cases	Total Deaths	Deaths/ 1M Pop
Belgium	11.6	98%	42	584,707	53,449	8,707	751
Spain	46.8	80%	45	2,467,761	268,143	26,744	572
Italy	60.5	69%	47	2,565,912	219,070	30,560	505
United Kingdom	67.9	83%	40	1,821,280	219,183	31,855	469
France	65.3	82%	42	1,384,633	176,970	26,380	404
Sweden	10.1	88%	41	148,500	26,670	3,256	322
Netherlands	17.1	92%	43	265,156	42,788	5,456	318
Ireland	4.9	63%	38	214,761	22,996	1,458	295
United States	331.0	83%	38	9,445,445	1,368,036	80,789	244
Switzerland	8.7	74%	43	312,813	30,344	1,834	212
Canada	37.7	81%	41	1,135,984	68,848	4,870	129
Denmark	5.8	88%	42	326,560	10,513	529	91
Germany	83.8	76%	46	2,755,770	171,999	7,569	90
Iran	83.7	76%	32	601,324	109,286	6,685	80
Austria	9.0	57%	44	319,484	15,882	620	69
Brazil	212.6	88%	33	339,552	163,510	11,207	53
Finland	5.5	86%	43	123,300	5,984	271	49
Turkey	84.3	76%	32	1,370,598	138,657	3,786	45
Norway	5.4	83%	40	195,921	8,105	219	40
Iceland	0.341	94%	38	54,195	1,801	10	29
Israel	8.6	93%	30	461,704	16,492	254	29
Bahamas	0.393	86%	32	1,500	92	11	28
Mexico	128.6	84%	29	130,956	35,022	3,465	27
Russia	145.9	74%	40	5,636,763	221,344	2,009	14
South Korea	51.3	80%	44	668,492	10,909	256	5
Egypt	102.3	43%	25	90,000	9,400	525	5
Japan	126.5	92%	48	214,256	15,777	624	5
Australia	25.4	86%	38	855,119	6,948	97	4
Indonesia	273.5	56%	30	161,351	14,265	991	4
China	1,439.3	61%	38	NA	82,918	4,633	3
South Africa	59.3	67%	28	341,336	10,015	194	3
Pakistan	220.9	35%	23	294,894	30,941	667	3
India	1,380.0	35%	28	1,673,688	67,724	2,215	2
Bangladesh	164.7	39%	28	129,865	15,691	239	1
Nigeria	206.1	52%	18	23,835	4,399	143	0.7
Hong Kong	7.5	100%	45	168,291	1,048	4	0.5
Ethiopia	115.0	21%	19	36,624	250	5	0.04
Total Worldwide	7,794.8	56%	31	37+ million	4,210,318	284,448	37

Source: Worldometer (May 11, 2020)