

LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

Supply Constraints Still Limit Covid-19 Testing

It's been nearly two months since the first patient tested positive for Covid-19 in the United States on January 20. Nonetheless, labs are still reporting difficulty in obtaining nasal swab collection kits and test reagents that are keeping them from reaching their full capacity to perform Covid-19 testing. The supply bottleneck means that testing is being rationed to only the sickest patients showing symptoms of Covid-19. Likewise, there are signs that supply constraints will also limit the lab industry's ability to perform high volumes of new antibody tests for Covid-19 that are beginning to be introduced. This is stifling the nation's attempt to understand the spread of the virus and leading to monumental decisions being made without reliable data.

For example, Northwell Health Labs is based at the current world epicenter of the virus in New York. It has the capacity to perform more than 4,000 Covid-19 tests per day, but is limited to 2,000 tests due to supply constraints. "Our doctors are exercising a high degree of discretion as to who is tested and the lab industry is in a full sprint trying to get ahead of this virus," says James Crawford, Senior Vice President for Laboratory Services at Northwell Health.

Although the apex for Covid-19 hospitalizations and deaths in the New York City area may be near, Crawford warns that Covid-19 is "going to be in our population for a long time." For our full interview with Dr. Crawford, *see pages 3-4*.

The CARES Act — Not Much In It For Labs

The enormous \$2 trillion Coronavirus Aid, Relief and Economic Security Act (CARES Act) was signed into law on March 27, but provides little in direct relief to the nation's laboratories. The American Clinical Laboratory Assn. (ACLA) had lobbied for \$5 billion in new federal funding designated specifically for labs performing Covid-19 testing to cover uncompensated testing services, staffing and the purchase of analyzers, reagents and collection kits. Instead, the cornerstone healthcare provision of the final law is an ambiguous \$100 billion fund for entities "that provide diagnoses, testing, or care for individuals with possible or actual cases of Covid-19."

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The CARES Act — Notable Provisions For Labs (*cont'd from page 1*)

Below we summarize key provisions in the CARES Act that pertain to laboratories.

\$100 Billion Fund for Eligible Healthcare Providers

The single paragraph of the CARES Act that establishes the \$100 billion fund is vague and leaves the Department of Health and Human Services (HHS) with a major role in distribution decisions.

Eligible healthcare providers, including hospitals, physician practices and laboratories, must submit an application to HHS that includes their tax ID number and “a statement justifying the need of the provider for payment.” Provider expenses that may be reimbursed include “personal protective equipment and testing supplies.” Lost revenues that are attributable to coronavirus are also eligible to be reimbursed, but the Act does not explain how this will be calculated.

It's unclear how the \$100 billion will be divvied up. Applications will be reviewed by HHS on a rolling basis, but there are no details on how or when the money will be disbursed. HHS says it will be providing additional information on how healthcare providers and suppliers can access these funds in the coming weeks.

Coverage of Covid-19 Testing

Health plans/insurers are required to provide coverage, without cost sharing (including deductibles, copays and coinsurance) or prior authorization to hospitals and labs for all Covid-19 testing. Reimbursement is set at the negotiated rate for contracted labs. Non-contracted labs will get paid their list price, but are required to publish their test price on their website. For comparison, the Medicare CLFS rate for Covid-19 testing (CPT 87635) is set at \$51.33.

Medicare CLFS Rate Freeze

The Act freezes Medicare Clinical Laboratory Fee Schedule (CLFS) rates in 2021. Under PAMA, CLFS rates for most high-volume tests had been scheduled for cuts of 10% to 15% next year.

The Act also delays labs' responsibility to report their private-payer data to CMS under PAMA by another year to January –March 2022. This follows a previous one-year delay achieved with the year-end spending package.

Medicare Sequestration Temporarily Suspended

The annual 2% cut, or “sequester,” in Medicare fee-for-service claims (including the Medicare CLFS and Medicare Physician Fee Schedule) has been temporarily suspended from May 1 through the end of this year. However, the sequestration policy has been extended by an extra year (through 2030) in exchange for this temporary suspension. The 2% reduction has been in effect since 2013 under the Budget Control Act of 2011.

Add-On Payment for Hospital Covid-19 Patients

Hospitals will receive a payment increase of 20% for patients diagnosed with Covid-19 and later discharged during the emergency period. The discharge will be identified based on diagnosis codes, condition codes or other necessary means. This means Medicare's payment for these types of hospital stays could go from \$10,000 to \$12,000, depending on the severity of the illness.

ACLA on Lack of Dedicated Funding

“For the third time, Congress has failed to provide the necessary funds to support ‘free testing’ for all Americans. Our members remain in an untenable situation, absorbing growing, uncompensated costs for testing specimens with no assurance that they will be appropriately or fairly reimbursed for the tests they are performing,” according to a March 26 statement from ACLA President Julie Khani.

Spotlight Interview With Northwell's James Crawford

James Crawford, MD, PhD, oversees the integrated laboratory network for Northwell Health, which includes 23 hospital-based labs located throughout the New York City area and an 1,100-employee core lab based in Lake Success, NY. Here's a summary of Dr. Crawford's viewpoints on several key aspects of the Covid-19 pandemic.



*James Crawford,
MD, PhD*

How does Covid-19 compare with past outbreaks?

I worked closely with the head of infectious disease diagnostics at Northwell, Christine Ginocchio, PhD, back in 2009 during the H1N1 “swine flu” pandemic. H1N1 pales in comparison to the current Covid-19 crisis. I can hear the difference in the sense of desperation from our doctors and nurses. The ICU admission rate, length of stay and heartbreaking mortality rate for Covid-19 are all significantly higher. The risk of infection for our healthcare personnel is also much higher. The fact that asymptomatic Covid-19 patients are contagious makes this an extremely difficult virus to deal with. This is not just another respiratory virus. It is a frightening illness.

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

We brought the CDC's manual assay online on March 8 and are able to test 90 patients per day—the maximum volume based on the test kits we receive.

We began semi-automated testing using the GenMark platform on March 11, but are limited to 200 tests per day due to test kit supply restraints, despite a potential system capacity that is much higher.

We added Covid-19 testing on our fully-automated Hologic Panther analyzers on March 18. We have the capacity to run 1,100 tests per day on each analyzer, but again, are limited to a total of approximately 2,000 tests due to supply restraints. Put it all together, we have been capped at between 2,000 to 2,500 tests per day since March 18.

We're also considering adding analyzers from Cepheid and/or Diasorin to broaden our supply chain and increase capacity.

How is Northwell prioritizing its test orders?

Our highest priority specimens are for hospitalized patients with signs and symptoms of Covid-19—including specimens taken from Emergency Department visits; other symptomatic older adults or patients with chronic medical conditions or who are immunocompromised; hospitalized patients pending discharge to skilled nursing facilities and “front line” Northwell employees.

We're also increasingly testing “need to know” patients, including obstetric patients, patients entering into Covid-19 clinical trials, and patients scheduled for highly-invasive surgeries, such as ENT surgeries, for which Covid-19 exposure is high. In addition, we are now running pilots for more routine presurgical Covid-19 testing, in anticipation of the re-awakening of elective surgical procedures in our health system.

Lower priority testing is for Northwell employees who are not front-line, and for ad hoc prioritization of patients based on discussion with their ordering physicians.

What kind of positivity rates are you seeing?

Our percent positive rates for Covid-19 testing rose from 20% in early March to 70% by March 28. For the first week in April it has settled back to the 60% range. This extraordinarily high positivity rate tells us that we're only testing a fraction of the patients we'd want to be testing, ideally, if we had unlimited testing available. From an epidemiologic standpoint, I would feel more comfortable if we were performing sufficient testing in our communities so as to have positivity

rates down around to about 10%. It remains to be seen whether the slight decrement in our high positivity rates over the past week are a lead indicator of the New York area seeing a “plateau” in case incidence rate.

Where does Northwell’s bed and ICU capacity stand?

System wide we have 23 hospitals with about 5,000 staffed beds; expanded from about 3,800 beds before the start of this crisis. Nearly 60% of our beds (3,000) are currently occupied by Covid-19 patients, with 26% in the ICU. We think we’re in a good position to weather the storm. Given the prior outbreaks of H1N1, Ebola, and Zika, Northwell had stockpiled a lot of PPE and other supplies in anticipation of the next outbreak. To date, we have been able to maintain our PPE supply chains.

Have you seen increased demand for respiratory virus panels (RVPs)?

RVP orders have increased over eight-fold since the start of the Covid-19 crisis. This is unfortunate because the testing is 90% negative, and doing so negatively impacts the supply chain for Covid-19 tests. Every RVP that’s performed potentially represents a Covid-19 test that can’t be performed, both at the manufacturer’s end of the supply chain, and in using up capacity on the testing platforms. For positive Covid-19 cases, only about 3% also test positive for a RVP. And having another respiratory virus has no bearing on treatment for Covid-19. For Northwell at this time, RVP is not a useful test to be performing.

How has the Covid-19 pandemic affected Northwell’s routine test volumes?

At the start of the year, our core lab was performing an average of about 18,000 metabolic test panels per week and that’s declined to 13,000 per week. Our volume of CBCs with differential has fallen from 23,000 tests per week to about 8,000 tests per week. Our volume of 88305s, 88307s, and 88309s (surgical pathology) has also dropped substantially. In essence, routine doctor visits are being cancelled and surgeries are being postponed. We are preparing for routine testing and biopsies to roar back with vengeance after the Covid-19 crisis passes its peak.

Has Northwell begun antibody testing for Covid-19?

Northwell is intensively examining our options for Covid-19 serological testing. We have validated multiple commercial platforms, and are ready to go on several of them. Our decision-making over the coming 1-2 weeks hinges, again, on our access to the respective supply chains. Even if we limit our initial test offering to Northwell employees, we have potentially 70,000 tests to perform. This is before we begin testing pre-surgical patients and other hospitalized and ambulatory patients in need of such testing. We also need to prepare for serological qualification of Covid-19 convalescent plasma donors. Over time, the volume of antibody testing is expected to dwarf that of testing for Covid-19. We are mapping our serological testing strategy for short-term, intermediate, and long-term objectives, and are aiming to have in-house capacity and/or access to the testing capacity required for each phase of this deployment.

Describe Northwell’s involvement in clinical trials for Covid-19 treatments?

Northwell’s Feinstein Institutes is a participating institution in a randomized controlled clinical trial sponsored by Regeneron Pharmaceuticals and Sanofi. The objective is to assess the potential clinical efficacy of Sarilumab for inhibition of the IL-6 mediated host inflammatory response in Covid-19 illness. From March 18 to April 5, Northwell enrolled over 200 patients in this clinical trial. From initial consideration of this clinical trial on March 11, the entire clinical trials apparatus was set up in 6 days. This included Northwell Laboratories setting up a Covid-19 Clinical Trials “Biospecimen Processing Facility,” in order to rapidly process the extensive regime of blood samples required for this clinical trial. This has been a 7-days-a-week operation ever since, which is of further importance as additional randomized clinical trials come on-line at Northwell. We also are now broadening the service mission of this facility to procure a broad set of biospecimens from hospitalized patients, for the purposes of discovery of both biomarkers and potential targets for novel therapies.

Spotlight Interview With Viracor's Steven Kleiboeker

Viracor Eurofins Laboratories (Lee's Summit, MO) is a specialty laboratory focused on infectious disease, immunology and allergy testing for immunocompromised and critical patients. Viracor is a 100% subsidiary of Eurofins Scientific (Luxembourg). Under the FDA's Emergency Use Authorization Guidance, Viracor was one of the first private labs to introduce a laboratory-developed test (LDT) for Covid-19. *Laboratory Economics* recently spoke with Viracor's Steven Kleiboeker, PhD, Vice President of Research and Development.



*Steven Kleiboeker,
PhD*

Describe the current status of Viracor's Covid-19 testing?

We started Covid-19 testing on March 13 using our unique assay design which included EasyMag specimen nucleic acid extraction and Thermo's ABI 7500 analyzer and reagents. Our initial capacity was 1,000 tests per day with turnaround time within 24 hours of specimen receipt. We quickly ramped to 2,000+ tests per day with 2-3 day TAT. Our sister lab in Alabama, Diatherix Eurofins, is also performing Covid-19 testing with capacity of 2,000 - 3,000 tests per day.

A large percentage of those tests are processed within 24 hours. However, due to a small backlog, unprecedented demand, pressures on our supply chain, and shipping delays (some of which are related to specimen quality), our turnaround time for some clients has been pushed beyond what we normally experience. At most, we are looking at a 2-3 day TAT.

Ultimately we expect to get turnaround times across-the-board back down below 24 hours, but right now, the greatest need is for increased testing capacity. Both labs are running 24/7 at full capacity and we still can't meet the demand for testing. We have increased capacity by adding an additional platform (Abbott).

Are you encountering any supply shortages?

The supply chain is stretched and we're doing all we can to stay half-a-step ahead. Specimen collection kits and swabs are a choke point. It's hard to find the preferred universal transport media (UTM) collection kits, so we're now looking at viral transport media (VTM) kits and phosphate buffered saline (PBS) as an alternative to keep specimen swabs moist during transport. Beyond swab and sputum samples, we are also exploring other specimen types.

Why did Viracor and Diatherix developed their own assays?

Instead of developing a single test, Viracor Eurofins and our sister lab, Eurofins Diatherix, leveraged our unique capabilities, techniques and equipment to develop a proprietary, molecular SARS-CoV-2 assay for Covid-19. This approach allowed each lab to go-to-market faster and because of the anticipated supply chain issues, it also allowed us to stratify risk across suppliers.

Diatherix uses a proprietary technology, TEM-PCR (Target Enriched Multiplex Polymerase Chain Reaction) for precise detection of infectious diseases at high levels of sensitivity and specificity, and at very short turnaround times. It's also a cost-effective way to multiplex several different respiratory pathogens.

If requested, the Diatherix assay for Covid-19 can be combined with other respiratory tests, producing results highly comparable to a standalone Covid-19 test.

Are you seeing prices rise for gloves, collection kits and swabs as a result of the shortages?

While there is pricing variability in this space, my impression is that prices have not increased with increased demand.

Where are your Covid-19 test orders coming from?

We provide reference testing services to approximately 200 academic medical centers and hospitals and that's where the orders are coming from. We've added 10-20 new clients in the past few weeks. Hospitals are sending samples to wherever they can get the test result the fastest, whether that's a state public health lab or private lab.

Are most Covid-19 tests being ordered in conjunction with a respiratory virus panel?

The combination of a Covid-19 test and respiratory virus panel and/or flu test is necessary because 4-7% of cases have co-infections (simultaneous infection by two or more viruses).

Are you working on an antibody test for Covid-19?

Another Eurofins lab subsidiary, Boston Heart Diagnostics (BHD), has developed a Covid-19 antibody test that was launched in early April. The blood-based antibody test identifies people who were exposed and developed an immunity to Covid-19, but potentially had mild to no symptoms. This test—unlike the NP swab which determines active infection—is a crucial next step in fighting the spread of Covid-19. Antibody testing should be done at least 14 days after exposure. Viracor will also soon be introducing a Covid-19 antibody test.

Given the overwhelming demand in acute care settings, the test will be initially offered to hospitals nationwide. As capacity increases, we will begin testing less acute patient populations, eventually allowing those with immunity to get out of quarantine and back to work.

Initial capacity will be nearly 5,000 tests per day, or 200 results every hour. Hospitals along the east coast, including those in hot-spot areas, will have the option to courier specimens to BHD for results in just hours. Speed is crucial to helping first responders and healthcare providers assess their ability to be on the front lines. Once Viracor's antibody assay is launched, we expect daily capacity to increase.

Are other test volumes declining because people are staying home/less doctor visits?

Testing not related to Covid-19 has declined overall for a variety of reasons—people are staying home, not wanting to put themselves at risk by going to the hospital, etc. However, if you look at some of our most critical tests, like viral load testing, antiviral drug resistance testing, and immunology testing, the volume is mostly unchanged.

What precautions are you taking to protect lab employees from getting the virus?

It's incredibly important that our lab scientists stay healthy. We have about 150 lab employees at Viracor and all non-essential lab personnel that can work from home are doing so. We've made it clear that any employee with symptoms should stay home and we're taking the temperature of every employee before they enter the lab.

Do you see any similarities when compared to past outbreaks like Swine Flu, Zika or Ebola?

This really is unprecedented and will be a serious public health issue for at least the next few months, not weeks.

Could the warmer more humid weather in the spring/summer slowdown the spread of Covid-19?

Other respiratory viruses have been most problematic in the colder months when more people are together in enclosed rooms. The warmer months may bring some relief, but won't be the savior.

What signs would tell you that the worst is over from Covid-19 in the United States?

If cases stabilize or decline, that would certainly be a good sign. However, it could be due to warmer weather, social distancing or some other unknown factor. However, if any of those known (or unknown) factors reverse, or others come into play, we could certainly see another period of increasing cases.

Spotlight Interview With BioReference's Jon Cohen

BioReference Laboratories (Elmwood Park, NJ), a subsidiary of OPKO Health, is one of the nation's largest full-service clinical laboratories. Formerly a senior executive at Quest Diagnostics, Jon Cohen, MD, became Executive Chairman of BioReference Labs in January 2019. Below Dr. Cohen provides an update on Covid-19 testing at BioReference.



Jon Cohen, MD

Can you describe your drive-through testing sites?

We have contracts to provide Covid-19 testing for more than 20 drive-through testing sites in New York, New Jersey, Detroit and Miami. They are client-bill type contracts with the New York State Department of Health, the New York City Health and Hospital Corporation (NYC Health + Hospitals), the State of New Jersey, the cities of Detroit and Miami, and some private medical groups.

The collection sites have been set up at various locations including parking lots at hospitals, state parks, colleges, stadiums and malls. Patients are required to have a doctor's order and to call ahead for an appointment.

All specimens are transported to BioReference's main laboratory in northern New Jersey, which currently has a capacity to run up to 20,000 Covid-19 tests per day, which will soon be increased to 35,000. We use four instrument platforms to test for Covid-19 with the majority of our testing done on Roche cobas and Thermo Fisher systems. To date, BioReference has tested more than 200,000 patients for Covid-19.

Who does the specimen collection at the drive-through testing sites?

Each site is different; some sites are using county Department of Health staff with support from medical staff from local hospitals or large medical centers in the area. The key is the private-public partnership working together.

Roughly how many specimens are collected on average at each drive-through testing site per day?

This depends on the testing site itself, how many lanes, how many hours they are open, etc. On average, we have seen 4-5 appointments per hour per lane. [For example, a site with six collection lanes operating from 8 a.m. to 8 p.m. would collect roughly 300 patient specimens per day.]

Are you experiencing any shortages in test supplies?

We are seeing tight supplies of swabs and related collection media, but that hasn't stopped us from testing yet.

What are turnaround times for test results?

Overall, 24-48 hours. We're prioritizing hospital patients for TAT within 24 hours.

Who is getting tested?

It's primarily focused on symptomatic patients meeting CDC guidelines for testing. There needs to be more testing of doctors, nurses and first responders (police, firemen and EMTs). In addition, at some point in the near future, the public health labs and/or private labs need to start performing general population surveillance testing to monitor progress against the pandemic.

How has the Covid-19 crisis affected routine test volumes at BioReference?

Considering people are not going to the doctor's office for wellness visits or their elective surgeries have been rescheduled or postponed, we have seen a decrease in the volumes of our more routine tests.

Is BioReference currently performing a blood-based Covid-19 antibody test?

Not at this time.

Spotlight Interview with ARUP Laboratories' Julio Delgado

ARUP Laboratories (Salt Lake City) began PCR testing for SARS-CoV-2 – the virus that causes Covid-19 – March 12 and is currently able to run about 3,000 tests per day. Due to supply constraints, ARUP announced March 16 that it would focus SARS-CoV-2 PCR testing on clients within the state of Utah. *Laboratory Economics* recently spoke with Chief Medical Officer Julio Delgado, MD, about the pandemic and what ARUP is doing to ramp up testing.



Julio Delgado,
MD

Is ARUP's Covid-19 test volume primarily for symptomatic hospital patients?

The majority of the samples we are doing are from symptomatic patients and healthcare workers. We also are supporting drive-through testing. (As of April 12, Utah had tested more than 45,000 residents and had 2,207 confirmed cases of Covid-19 and 18 deaths.)

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

Everything has been a challenge, every single aspect of this. Anything we need to do this test we have run into supply chain issues—collection devices, media for transport, reagents, instrumentation, everything. We can only promise five days ahead of time in terms of our capacity. It was really bad in the beginning, and it's a little better now, but it's still a challenge. We don't have long term commitments from any vendors for supplies.

Are most coronavirus tests being ordered in conjunction with a respiratory virus panel?

We saw that initially, but that has decreased. It started with a one-to-one ratio, then it went to two-to-one, five-to-one—now it's approximately twenty-to-one. The two tests are run on the same instrumentation. In Utah, clinicians are focused primarily on Covid-19 as we move out of the winter.

How many coronavirus tests can your lab perform per day?

We have capacity for about 3,000 a day. The challenge is that because we cannot secure a continuous supply chain, we can only take so many samples.

Are test orders exceeding capacity?

Since we closed the national offering, we have managed much better. We got completely flooded—in the beginning we had thousands of orders coming in. I believe we made the right decision for patient care to stop testing nationally. Of those initial national requests, we processed several internally, and we sent some to commercial reference laboratories, but they were backlogged, too. We finally were able to report everything, but it took a long time.

Does ARUP currently perform an antibody test for Covid-19?

Not today, but we are working on it. We are hoping to have it ready in a week or two. This will be used for convalescent individuals and people who think they may have had the virus. This will help determine if someone has developed immunity and whether they can go back to work.

Has ARUP seen a decline in non-Covid-19 testing?

Yes, absolutely. With 80% of the country at home, people are not going to medical checkups, elective surgeries are not being done. Non-Covid testing is down at least 25% and decreasing.

Which instrument system does ARUP use to perform Covid-19 testing?

We have been using Hologic instruments [Panther Fusion]. We are getting ready to start using Roche cobas, so we will be using both. We hope to be able to run more tests, beyond 3,000, but that depends on the supply chain.

What precautions are you taking to protect lab employees from getting the virus?

We are doing everything dictated by the CDC. So far, we have been lucky—none of our virology lab workers have contracted the virus as far as I know. Those who are running the tests are using N95 masks, face shields, gowns. So far, we have had enough personal protective equipment, but we have not been able to replenish it at the same rate we were before. The lab staff are keeping at least six feet apart.

Could the warmer more humid weather in the spring/summer slow down the spread of Covid-19?

I don't know.

What's your turnaround time for Covid-19 testing results?

We are promising within three to four days, but in most cases it's two days. Hologic is a random-access instrument, which allows us to incorporate testing and move things ahead – that way we can prioritize testing for very sick patients.

Are you doing any rapid testing?

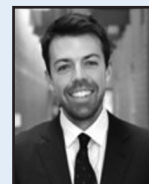
We have two BioFire instruments in the hospital system. They do one test at a time, and it takes about 45 minutes. We are using them judiciously in very critical and emergency situations. We also have several Abbott ID NOW instruments, and we have ordered tests, but areas with critical needs are being prioritized. We are on the list, and at some point we will get them.

Do you believe that surveillance testing of non-symptomatic people for Covid-19 is needed?

I believe so, but with the limitations of the supply chain, we aren't able to do that. Right now, testing is all reactive. Surveillance testing would give us a better understanding of the epidemiology and the curves that each of the states will go through.

Spotlight Interview with AHA's Chris Martin

American Health Associates (AHA-Miramar, FL) is an independent laboratory that operates 14 regional labs and serves more than 4,000 nursing homes and assisted-living facilities throughout the Southeast, Midwest, and Mid-Atlantic. Its biggest markets are Ohio, Florida, Kentucky, Michigan and Tennessee. Originally founded in 1990 by its Chief Executive Debbie Martin, AHA has grown to be one of the largest independent labs in the nation. *Laboratory Economics* recently spoke with AHA's President Chris Martin.



Chris Martin

Why are nursing home labs so critical to Covid-19 testing?

We employ more than 1,000 phlebotomists who are collecting specimens from the bedside of the nation's most vulnerable population each morning between 4 a.m. and 9 a.m. Phlebotomists drive specimens back to our labs for testing and results are reported same day to physicians for their afternoon rounds. It's a "high-touch" service with logistical challenges that the biggest commercial labs and many hospitals don't want to take on and aren't able to take on. Without nursing home labs, tens of thousands of elderly patients and their doctors would lose access to, or face delays, for critical tests like those for Covid-19.

Describe the current status of AHA's Covid-19 testing?

We currently send our Covid-19 test specimens to LabCorp. Within the next few weeks we are bringing in house tests to rule out viruses that have similar clinical indications to Covid-19 using Thermo's QuantStudio at our corporate lab in Davie, Florida (near Miami).

Are you experiencing any supply shortages?

There's definitely a shortage of specimen collection kits (swabs) and personal protective equipment (gowns, gloves and masks). The good news is that manufacturers are ramping up production, and

we have not experienced directly any price gouging to take advantage of the shortages so far.

What steps are you taking to protect your employees and nursing home patients?

We're still in the early days of this pandemic, but so far none of our employees has tested positive. We are emphatically telling employees to stay home if they are showing any signs of symptoms, have been in contact with someone that's been exposed, or recently traveled outside the U.S. Nursing homes are checking the temperature of all their employees and our phlebotomists before they enter the building.

Can you describe how the nursing home population has become more acute?

Covid-19 has only accelerated the extent to which skilled nursing facilities are taking on sicker patients. In many ways skilled facilities are now, more than ever, clinical extensions of the broader hospital system in the United States, especially in the wake of the 1135 waivers that the President issued under the Stafford Act. One waiver was of the three-day inpatient stay requirement for a patient to be eligible for a stay in a skilled nursing facility. This waiver will allow hospitals to discharge more patients to create more room for Covid-19 patients. More broadly, we feel very much that we are a part of the hospital system; that we in turn have to function as a lab as if we were in the four walls of that facility; the same way hospital labs function.

How have the PAMA rate cuts affected AHA?

The majority of our revenue is either directly or indirectly tied to the Medicare CLFS, so the past three years have been challenging. We've gotten more efficient through cooperation with our clients, investing in information systems and better contracts with our vendors.

Your thoughts on the new relief package that includes a freeze on Medicare CLFS rates in 2021?

Regarding the CARES Act, we are hopeful that we'll be eligible for relief under the Public Health and Social Services Emergency Fund which we hope will protect vital access to testing and other essential healthcare services for those most in need and especially residents in nursing facilities.

The delays in the cuts that would have otherwise happened in 2021 is a good thing for the industry and especially laboratories, like AHA, that serve nursing homes, because of how much of our payment is derived either directly or indirectly from the CLFS. Developing private payer rates for our services is actually quite challenging even with some of the robust financial and laboratory systems that AHA has. It involves examining contracts along with reimbursement rates in actuality and looking at these over time and at scale to develop an accurate understanding of reimbursement rates.

Are nursing home labs consolidating as a result of reimbursement pressure?

AHA roughly doubled in size through the acquisition of the nursing home division of MEDLAB (Cincinnati) in late 2014. More recently, a number of hospitals and independent labs in Florida, Michigan and Indiana have stopped serving their nursing home clients and we've picked up many of those contracts. The national market seems to be shaking out to four main nursing home lab companies: AHA, Trident, Aculabs and Gamma Healthcare.

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Sweden Takes Measured Approach To Covid-19 Pandemic

Sweden's Prime Minister Stefan Löfven has asked all citizens to avoid non-essential travel and to stay home if feeling sick or over the age of 70, but has stopped far short of the stricter emergency measures enacted by most other countries.

Gatherings of more than 50 people are banned and nursing homes are closed to visitors, but Sweden's restaurants, bars, malls, gyms, hair salons and cinemas all remain open. High schools and universities are closed, but children under age 16 continue to go to pre-schools and primary schools.

While Löfven has drawn criticism for his "business as usual" policy, it's actually based on data from Sweden's highly-independent Public Health Agency and its Chief Epidemiologist, Anders Tegnell, MD, PhD.

On March 22, Tegnell told Swedish TV that he expects the outbreak will "calm down" in May but return in the autumn. "It will be important how much of the population is infected," he said. "It will determine what happens in the autumn." Coronavirus could be stopped either by "herd immunity, or a combination of immunity and vaccination," he said. "It's basically the same thing."

Sweden believes its less-restrictive policy can be maintained for a longer period of time compared with a national lockdown.

A vaccine for Covid-19 is not expected to become available for at least one year.

"We are just trying to slow it, because this disease will never go away. If you manage, like South Korea, to get rid of it, even they say that they count on it coming back. Stopping it might even be negative, because you would have a pent-up possible spread of the disease, and then once you open the gates, there is a possibility that there would be an even worse outcome," according to Tegnell.

Sweden's less-intensive mitigation strategy should allow it to reach the herd immunity threshold (estimated at 60%) quicker and lower the country's risk of further waves of Covid-19, according to Paul Franks, PhD, Professor of Genetic Epidemiology, and Peter Nilsson, MD, PhD, Professor of Internal Medicine – Epidemiology. They are both based at Lund University in Sweden.

"Banning public gatherings is an idiotic idea," said Johan Giesecke, MD, PhD, an advisor to the World Health Organization and a senior professor at the Karolinska Institute in Stockholm. In an April 2 interview broadcast on *Public Radio International*, Giesecke said that closing borders, schools and restaurants have never been proven to have any effect. "If you don't have any science behind actions that may hurt the economy and social life, then why take them? There's one reason and that is that politicians want to show action, strength, decisiveness....It's a political thing." He said that the only preventative measure that has sound scientific backing is washing your hands. "But we've known that for 150 years."

However, not all scientists in Sweden support their country's Covid-19 strategy.

Marcus Carlsson, MD, PhD, a mathematician at Lund University, says that Sweden's "controlled-spread" strategy is "Like trying to pull the majority of the population through a key hole." In a video posted to YouTube on March 19, Carlsson noted that Sweden has only 500 ICU hospital beds for its population of 10 million. "We're being herded like a flock of sheep towards disaster."

Sweden's closest neighbors—Denmark, Finland and Norway—have chosen a lockdown strategy, closing schools, workplaces and borders weeks ago. "The problem with that approach is you tire the system out," Tegnell told *The Guardian*. "You can't keep a lockdown going for months—it's impossible."

Other countries that have taken a less-restrictive policy toward fighting Covid-19 include Brazil, Iceland and Japan. Only time will tell which strategy is best.

Lab Stocks Down 13% Year To Date

Twenty lab stocks have fallen by an unweighted average of 13% year to date through April 9. In comparison, the S&P 500 Index is down 14% so far this year. The top-performing lab stocks thus far in 2020 are Biocept, up 23%, and Vermillion, up 16%. Shares of LabCorp are down 13%, while Quest Diagnostics is down 16%.

Company (ticker)	Stock Price 4/9/20	Stock Price 12/31/19	2020 Price Change	Current Assets (\$ 000)	Current Liabilities (\$ 000)	Current Ratio (as of 12/31/19)
Biocept (BIOC)	\$0.36	\$0.29	23%	\$13,890	\$5,560	2.5
Vermillion Inc. (VRML)	0.94	0.81	16%	13,410	3,980	3.4
CareDx (CDNA)	21.89	21.57	1%	71,920	34,830	2.1
Opko Health (OPK)	1.43	1.47	-3%	324,045	249,119	1.3
Natera (NTRA)	32.17	33.69	-5%	523,170	179,870	2.9
DermTech Inc. (DMTK)	11.76	12.40	-5%	17,150	5,722	3.0
Interpace Biosciences (IDYG)	4.67	5.00	-7%	17,720	8,490	2.1
Enzo Biochem (ENZ)	2.44	2.63	-7%	71,100	23,200	3.1
NeoGenomics (NEO)	27.11	29.25	-7%	290,740	63,900	4.5
Guardant Health (GH)	68.87	78.14	-12%	597,360	72,730	8.2
LabCorp (LH)	146.80	169.17	-13%	2,981,200	2,655,800	1.1
Quest Diagnostics (DGX)	89.77	106.79	-16%	2,490,000	1,990,000	1.3
Invitae (NVTX)	13.29	16.13	-18%	442,400	81,860	5.4
Castle Biosciences (CSTL)	28.05	34.37	-18%	116,680	15,290	7.6
Veracyte (VCTT)	22.45	27.92	-20%	187,690	17,470	10.7
Sonic Healthcare (SHL.AX)*	22.84	28.75	-21%	1,449,043	2,063,352	0.7
Exact Sciences (EXAS)	67.06	92.48	-27%	556,959	236,494	2.4
Psychemedics (PMD)	5.45	9.15	-40%	12,850	5,840	2.2
Exagen (XGN)	15.00	25.40	-41%	81,250	5,900	13.8
Myriad Genetics (MYGN)	15.25	27.23	-44%	365,300	112,400	3.3
Unweighted Averages			-13%	\$10,623,877	\$7,831,807	1.4

*Sonic Healthcare's current assets and current liabilities are in Australian dollars as of 12/31/2019.

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

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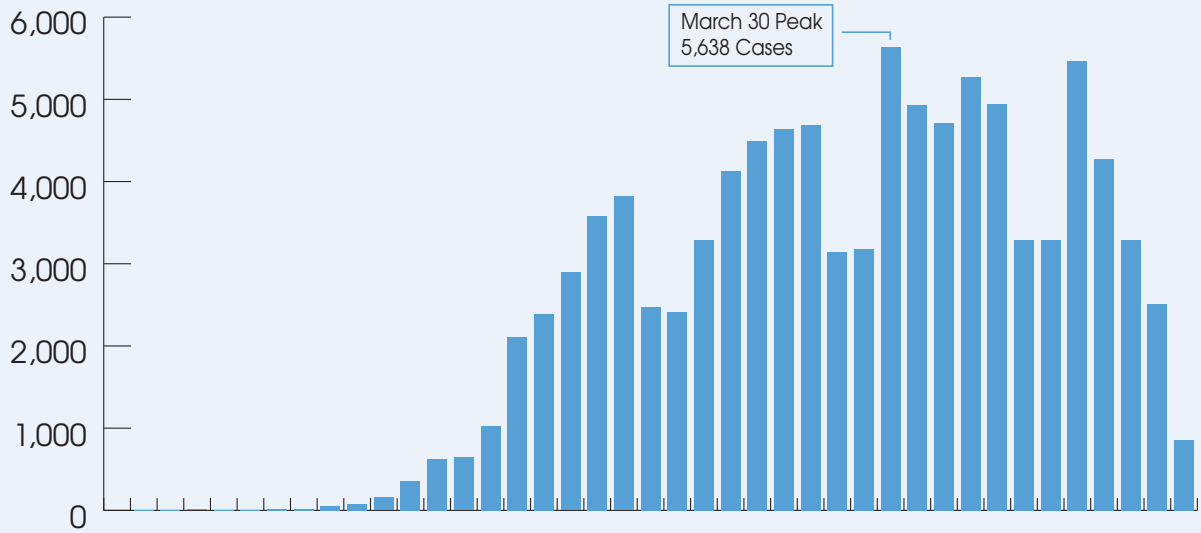
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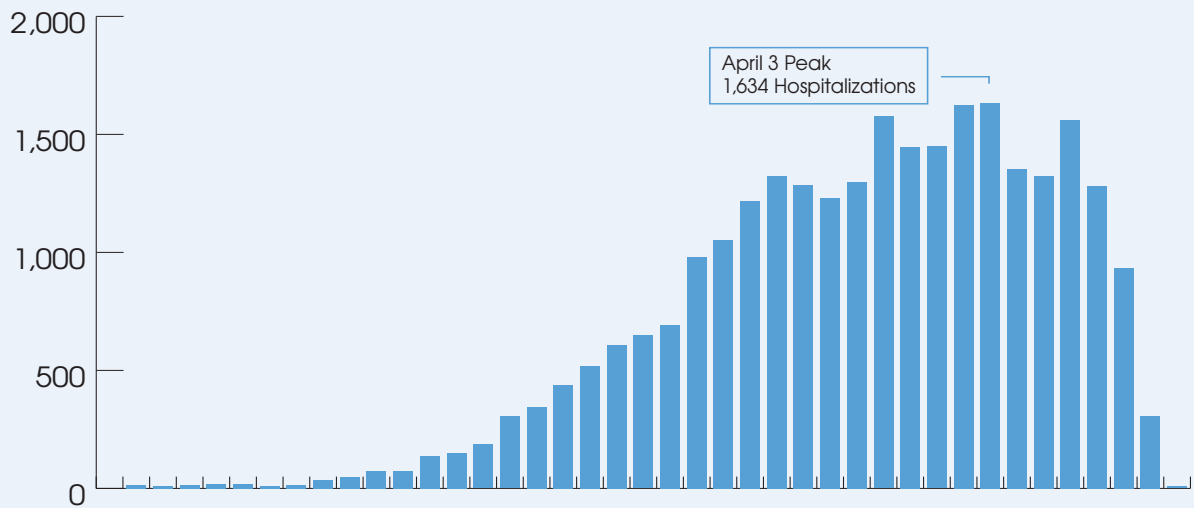
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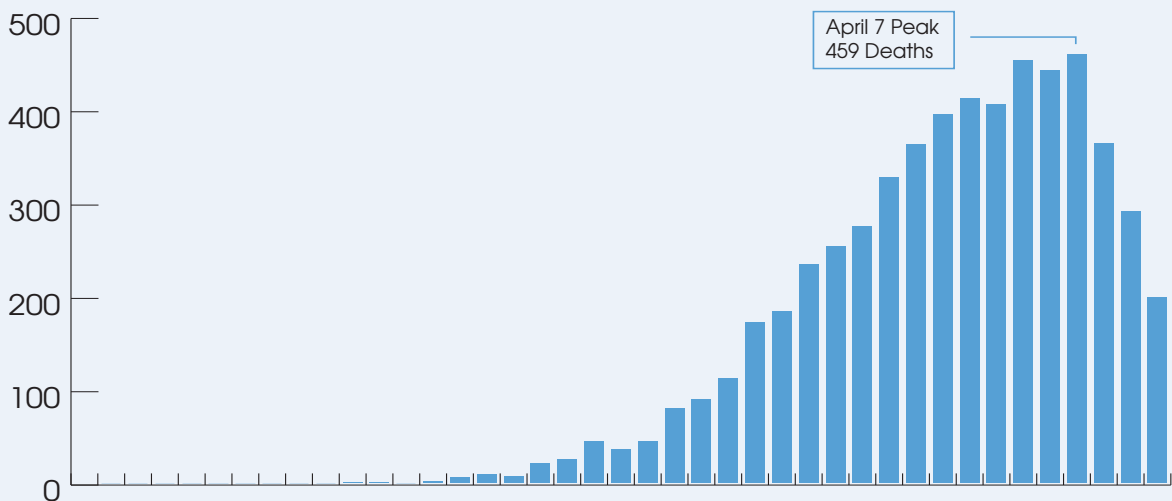
New York City Daily New Cases of Covid-19 (March 2 through April 10, 2020)



New York City Daily New Hospitalizations from Covid-19 (March 2 through April 10, 2020)



New York City Daily Deaths from Covid-19 (March 2 through April 10, 2020)



Source: NYC Department of Health and Mental Hygiene

Covid-19 Statistics for Select Countries (as of morning of April 12)

<i>Country</i>	<i>Population (millions)</i>	<i>Urban Pop %</i>	<i>Median Age</i>	<i>Total Tests</i>	<i>Total Cases</i>	<i>Total Deaths</i>	<i>Deaths/ 1M Pop</i>
Spain	46.8	80%	45	355,000	166,019	16,972	363
Italy	60.5	69%	47	963,473	152,271	19,468	322
Belgium	11.6	98%	42	102,151	29,647	3,600	311
France	65.3	82%	42	333,807	129,654	13,832	212
Netherlands	17.1	92%	43	101,534	24,413	2,643	154
United Kingdom	67.9	83%	40	334,974	78,991	9,875	145
Sweden	10.1	88%	41	54,700	10,151	887	88
Ireland	4.9	63%	38	53,000	8,928	320	65
United States	331.0	83%	38	2,693,758	533,115	20,580	62
Iran	83.7	76%	32	263,388	71,686	4,474	53
Denmark	5.8	88%	42	67,771	5,996	260	45
Austria	9.0	57%	44	144,877	13,945	350	39
Germany	83.8	76%	46	1,317,887	125,452	2,871	34
Norway	5.4	83%	40	126,486	6,459	123	23
Iceland	0.341	94%	38	34,635	1,689	8	23
Canada	37.7	81%	41	401,552	23,318	653	17
Turkey	84.3	76%	32	340,380	52,167	1,101	13
Israel	8.6	93%	30	117,339	10,878	103	12
Finland	5.5	86%	43	45,019	2,974	56	10
Brazil	212.6	88%	33	62,985	20,964	1,141	5
South Korea	51.3	80%	44	514,621	10,512	214	4
China	1,439.3	61%	38	NA	82,052	3,339	2
Australia	25.4	86%	38	353,941	6,313	59	2
Mexico	128.6	84%	29	35,479	4,219	273	2
Egypt	102.3	43%	25	25,000	1,939	146	1
Indonesia	273.5	56%	30	19,452	4,241	373	1
Japan	126.5	92%	48	68,771	6,748	108	0.9
Russia	145.9	74%	40	1,200,000	15,770	130	0.9
Hong Kong	7.5	100%	45	96,709	1,005	4	0.5
Pakistan	220.9	35%	23	61,801	5,170	88	0.4
South Africa	59.3	67%	28	75,053	2,028	25	0.4
Bangladesh	164.7	39%	28	9,653	621	34	0.2
India	1,380.0	35%	28	189,111	8,504	289	0.2
Nigeria	206.1	52%	18	5,000	318	10	0.05
Ethiopia	115.0	21%	19	3,863	71	3	0.03
Total Worldwide	7,794.8	56%	31	11+ million	1,795,747	110,005	14

Source: Worldometer (April 12, 2020)