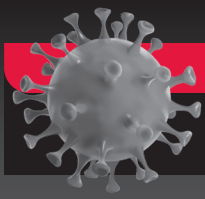
Volume XXVII, Number 5 Monday, March 30, 2020

Specialized Information Publishers Foundation
EDITORIAL EXCELLENCE AWARD WINNER



SPECIAL ISSUE!
Labs Respond to Coronavirus Pandemic

From the Desk of R. Lewis Dark...

THE DARK REPORT

RELIABLE BUSINESS INTELLIGENCE, EXCLUSIVELY FOR MEDICAL LAB CEOs / COOs / CFOs / PATHOLOGISTs

Restricted information, see page 3

COMMENTARY & OPINION by...

R. Lewis Dark
Founder & Publisher

Lab at the Epicenter of NY's Coronavirus Pandemic

TODAY, THE NOVEL CORONAVIRUS PANDEMIC DOMINATES the daily activities of every clinical laboratory in the United States. The emergence of COVID-19 has triggered unprecedented actions by governments in different nations throughout the world.

Within this country, all 50 states reported SARS-CoV-2 infections. But it is New York State that was hit hardest early in this pandemic. Until recent days, the number of confirmed COVID-19 cases and deaths in New York represented half of all cases and deaths reported in the United States.

One lab that found itself at ground zero in this unprecedented outbreak of a novel coronavirus is **Northwell Health Laboratories**, located on Long Island. The lab team wanted to give THE DARK REPORT inside access to its urgent pandemic response strategies and actions so that their lessons learned could be shared on these pages to help labs everywhere better respond to the outbreak in the communities they serve.

That is how we learned that the Northwell lab team characterizes itself as being "in the epicenter of the epicenter." If New York State is currently the COVID-19 epicenter in the U.S., then the New York City metro is the epicenter of the outbreak in New York State because more than 50% of confirmed COVID-19 cases and deaths in the Empire State have happened in the NYC metro.

For this issue of THE DARK REPORT, the Northwell lab team provided up-to-the-minute information about how the lab is adding value in the way it supports local physicians, the 23 hospitals in its system, local and state public health officials, and even the Governor's staff. You'll also read details about the way the lab adapted its existing mobile phlebotomy service to go to patients' residences to collect nasopharyngeal swabs for COVID-19 testing (on pages 22-24). Another intelligence briefing on pages 11-13 describes how the Northwell Lab is supporting drive-up collection sites.

The editorial team here at THE DARK REPORT wants to recognize the willingness of the Northwell laboratory administration and managers to carve out time to work with us to share useful information about their crisis response to the SARS-CoV-2 pandemic. In that spirit, we offer this "shout out" to all the dedicated pathologists, laboratory scientists, and staff at the clinical laboratory and pathology division of Northwell Health. TDR

This Coronavirus Outbreak Will Change Lab Industry

Nation's labs were hamstrung by inflexible test regulations, slow decisions by healthcare officials

CEO SUMMARY: COVID-19 is causing a level of global disruption not seen since the influenza outbreak of 1918. This new infectious disease exposes flaws in the strategies and planning of public health officials and governments in the United States and abroad. In this country, news media quickly recognized that the unavailability of clinical lab tests for COVID-19 was primarily because healthcare regulators required labs to comply with requirements that were burdensome during a time of crisis.

IT'S BEEN MORE THAN 100 YEARS since the outbreak of a new infectious disease interrupted daily life globally on the scale of the current pandemic of the novel coronavirus SARS-CoV-2, which causes the disease now called COVID-19.

It was always anticipated that clinical laboratories in the United States would be on the front lines of efforts to help physicians diagnose a new infectious disease like COVID-19. But this new disease emerged and hopscotched around the world in ways that were not anticipated.

That also proved true for advanced planning. The COVID-19 pandemic demonstrated how the U.S. health system's long-established strategies and plans for responding to a new infectious disease proved inadequate when confronted by the problems created by the global COVID-19 pandemic.

One consequence of these planning failures is that the nation's infrastructure of clinical laboratories were regularly-mentioned by the national news media in their criticisms of how government officials responded to the outbreak of this new infectious agent.

In particular, news outlets criticized the time it took for the U.S. healthcare system to develop accurate, reliable tests for COVID-19. Another major criticism continues to be about the limited access that physicians, patients, and consumers have to COVID-19 tests.

It would be an understatement to say the pathologists, clinical chemists, and medical laboratory scientists are equally frustrated about these same two issues. In particular, medical laboratory professionals know that those labs best-positioned to quickly develop, validate, and provide significant

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THE DARK REPORT Intelligence Briefings for Laboratory CEOs, COOs, CFOs, and Pathologists are sent 17 times per year by The Dark Group, Inc., 21806 Briarcliff Drive, Spicewood, Texas, 78669, Voice 1.800.560.6363, Fax 512.264.0969. (ISSN 1097-2919.)

R. Lewis Dark, Founder & Publisher. Robert L. Michel, Editor.

SUBSCRIPTION TO THE DARK REPORT INTELLIGENCE SERVICE, which includes THE DARK REPORT plus timely briefings and private teleconferences, is $15.27 per week in the US, $15.27 per week in Canada, $16.05 per week elsewhere (billed semi-annually).

numbers of COVID-19 tests in support of patient care were unable to respond quickly because of government regulations and decisions by public health officials in how COVID-19 testing would be handled in the earliest days of the outbreak.

COVID-19 Cases on the Rise

As of this date, the reported daily increase in the number of new COVID-19 cases indicates that the pandemic in the United States continues to intensify. But one positive development in the effort to contain this pandemic in the U.S. is that the availability of COVID-19 lab tests is ramping up at rates that are almost exponential.

This happened quickly once officials at the **Centers for Disease Control and Prevention** (CDC) and the **Food and Drug Administration** (FDA) loosened the regulatory handcuffs on the nation's clinical laboratory organizations.

The ability of a growing number of lab organizations to perform substantial volumes of COVID-19 testing could not come at a better time. Most clinical labs in the United States are experiencing a dramatic decline in revenue, for a simple reason—fewer people are visiting their doctors and hospitals are admitting fewer inpatients for conditions other than COVID-19. That is why labs are experiencing considerable declines in the number of specimens referred daily for testing, along with the lost revenue that would come from those same claims.

Making Up for Lost Revenue

Thus, the ability to replace that lost test volume with a significant number of COVID-19 tests—for which health insurers must reimburse—is a godsend for labs that can perform COVID-19 tests. However, because many community laboratories and community hospital laboratory outreach programs are way down on the list for distribution of COVID-19 kits from IVD companies, these labs may not get enough of these kits to help offset the revenue loss from the decline in their daily test referrals.

This decline in daily specimen volume, and the revenue loss associated with those tests hitting labs large and small across the United States, has gone unreported. Therefore, one outcome from this COVID-19 outbreak may be the closure, bankruptcy, or sale of community lab companies and hospital lab outreach businesses.

This will happen because the novel coronavirus outbreak is causing a substantial loss of daily revenue. When that revenue loss is added to the significant erosion of revenue over the past years due to the PAMA price cuts to the Medicare Part B Clinical Laboratory Fee Schedule—compounded by similar price cuts enacted by private health insurers—the cumulative revenue loss from these factors will tip a significant number of lab organizations into operational losses too great to overcome.

Dysfunctional Response

If, in coming months, the United States experiences a wave of clinical laboratory closures or sales, that won't be the only disruptive consequence of the 2020 COVID-19 outbreak. The pandemic has allowed the American public to see the disfunctions in several public institutions that have responsibility for responding to outbreaks of disease.

Stated differently, many important, long-standing assumptions as to how the government, regulatory agencies, Congress, and state officials would respond to a public health emergency—such as the outbreak of a new infectious disease—have proven to be out-of-date. One simple explanation for this is that society has moved forward in steady steps, but government institutions and political thought have remained anchored in cultural norms of older generations.

This outbreak revealed the mismatch between consumers who use new technology and are willing to share private information about themselves, and a government organized to respect individual rights—with limits on how it gathers and uses information about its citizens.

Can Clinical Labs, Pathology Ever Produce a National Figure Like a Dr. Fauci or a Dr. Oz?

ONCE AGAIN, THE PROFESSIONS OF LABORATORY MEDICINE AND PATHOLOGY lost a golden opportunity to educate the American public, the news media, and elected officials about why lab testing is essential to speedy and accurate diagnosis, particularly during the widespread outbreak of a novel infectious disease like SARS-CoV-2.

Back in January and February, as the first cases of COVID-19 were diagnosed in the United States, news reporters were quick to call labs throughout the nation and ask the pathologists and PhDs to answer two questions. First, why was it taking so long for COVID-19 tests to be available for physicians to use with their patients? Second, why have so few COVID-19 tests been performed in the United States, particularly when compared to countries such as China and South Korea?

Missing a Big Opportunity

However, at this moment of heightened national attention about the availability of an accurate medical laboratory test that could identify SARS-CoV-2, the pathology profession and the clinical laboratory industry missed its biggest opportunity in decades. It failed to produce one or more national experts who could educate all stakeholders about these points:

- Why laboratories and the tests they perform are literally the only clinical tool physicians can use to diagnose and manage every aspect of an infectious disease outbreak, particularly a new one like SARS-CoV-2;
- How federal and state laws and regulations prevented qualified labs from moving rapidly to develop and validate accurate tests for SARS-CoV-2; and,
- Similarly, how these same federal and state laws caused delays in how labs could move validated new COVID-19 assays onto automated platforms, thus allowing them to perform high-volumes of tests during the earliest stages of this COVID-19 outbreak.

A Public Face for Labs?

As of today, the clinical laboratory profession lacks a pathologist, a PhD, or a lab scientist who can be the public face of laboratory medicine—an expert trusted by the news media and the public, an expert who has credibility with presidents, governors, and healthcare policymakers.

Two examples illustrate the vacuum that exists in pathology and laboratory medicine. Think of Anthony S. Fauci, MD, Director of the **National Institute of Allergy and Infectious Disease** (NIAID) since 1984. At the moment, he is one of the best-known physicians in the United States. He stands next to the President during daily COVID-19 news briefings. He is interviewed multiple times per day on every cable news station.

Similarly, think of Mehmet Öz, MD, who is a cardiothoracic surgeon and on staff at **New York-Presbyterian Hospital**. Thanks to his exposure on the Oprah Winfrey show years ago, he's become a go-to expert on all things medical for news reporters and the American public.

Given these two nationally-known physicians, what if a reporter from the *New York Times*, *The Wall Street Journal*, or a cable news channel like *CNN* or *Fox* wants to interview an expert on clinical laboratory medicine and anatomic pathology? Who could they call today who can speak as an expert on the subject and will be immediately recognized and trusted by the American public?

Certainly the time is ripe for the lab profession to develop an expert who can tell the lab test story in a media-savvy manner.

In many ways, it is a simple case of science and society moving ahead at a pace that far exceeds the capabilities of government to recognize these changes and respond to them with solutions that are acceptable to the voting public. It is appropriate to mention here that vested interests that benefit from the status quo represent formidible barriers to elected officials who recognize the need to update and reform certain laws and regulations. These vested interests are consistently effective at keeping government locked into a status quo that is contrary to the interests of average citizens.

Response to COVID-19

Notwithstanding the institutional inertia of government and bureacracies, it can be expected that there will careful study of the monumental failures in how the U.S. healthcare system recognized the novel coronavirus outbreak and responded to it.

One likely change to benefit the clinical laboratory industry will be long-overdue reforms in how regulators oversee both clinical laboratories and research laboratories. As you will read on pages 25-26, several research labs in the United States quickly developed an accurate test for COVID-19, but were stopped by state and or federal regulators from using those tests against patients known to be infected by some type of respiratory virus.

Similarly, clinical labs certified under CLIA had to comply with regulations issued by the CDC, the CMS and the FDA. Also, as all three Federal agencies reacted to the COVID-19 outbreak, they issued new rules and guidance which sometimes prevented clinical laboratories from moving more quickly to validate COVID-19 tests and make them available to physicians and hospitals.

In some cases, these new rules and guidelines were changing daily, thus creating more uncertainty and delays for labs working to develop their own COVID-19 tests.

On the topic of clinical laboratory testing, the CDC, CMS, and FDA will need to recognize new technologies and how they advance the art and science of diagnostics. Benefiting from regular scientific breakthroughs are gene sequencing, molecular diagnostics, analytics, machine learning, and artificial intelligence.

Use of New Technologies

It is true that elected officials and government regulators did not make speedy use of new technologies here in the U.S. that were successfully deployed in other tech-savvy nations as they worked to control their own COVID-19 outbreaks.

Consider the multi-year interminable skirmishing over whether or not the FDA should regulate laboratory-developed tests (LDTs) in this country, with how quickly multiple labs in South Korea, China, Taiwan, and Singapore were able to develop and validate COVID-19 tests and make them available to doctors in their respective countries.

Smart Uses for Smartphones

Another challenging issue for Congress and regulatory agencies is how to leverage the smartphones, websites, and software apps citizens could use during disease outbreaks to stay informed and learn how to access physicians, hospitals, and other healthcare providers, while also protecting the individual's privacy.

Additionally, widespread use of smartphones offers healthcare systems new, unimagined ways to follow a disease outbreak. Smartphones can be a way to identify people exposed to a new disease and track them as a way to identify who else may have been exposed to the disease.

Once this COVID-19 outbreak ends, all of these issues will confront lawmakers and regulators, though they may not have much time if COVID-19 reappears in strength at the start of next fall's influenza season. **TDR**

—Robert Michel

Contact Robert Michel at rmichel@dark-report.com.

Providers Get Creative as FDA Clears More IVD Firms' Tests

Hospital CEO mortgages his home to buy COVID-19 test kits; POC tests get FDA EUAs

CEO SUMMARY: Clinical and molecular test laboratories, hospitals, public health agencies, and other providers are taking unusual measures to expand the number of tests available to identify the spread of the new coronavirus. When a hospital needed funding to buy test kits for the disease, the president of the facility used his own personal funds. When two residents of a resort town in Colorado wanted to test all 8,000 residents in their county, they partnered with county health officials and their test company will pay for the tests.

EVEN AS MULTIPLE *IN VITRO* DIAGNOSTIC (IVD) COMPANIES were obtaining FDA EUAs for their COVID-19 tests, providers here and abroad were getting creative in their responses to the global outbreak of SARS-CoV-19.

After weeks of national news reports on regulatory hurdles preventing clinical labs from quickly delivering validated COVID-19 tests for clinical use, officials at the federal **Food and Drug Adminstration** (FDA) got the message: healthcare professionals and the American public wanted COVID-19 tests NOW!

In recent days, the FDA issued emergency use authorizations (EUAs) for a growing number of test kits and instruments used to perform the tests. Included were these three EUAs:

- An EUA on March 27 for **Abbott Laboratories** to offer its ID Now COVID-19 test, a point-of-care molecular test that physicians can use in their offices.
- An EUA on March 20 for **Cepheid's** Xpert Xpress SARS-CoV-2 point-of-care COVID-19 diagnostic test for use in CLIA-certified moderate- and high-complexity labs. Results are available in 45 minutes.
- An EUA on March 23 for **bioMérieux's** BioFire COVID-19 45-minute test for use in CLIA-certified moderate- and high-complexity labs. *(See sidebar, "In Recent Days, at Least Three Companies Get EUAs for Point-of-Care and Rapid-result COVID-19 Tests," page 9.)*

Home Equity to Fund Tests

Two examples of innovative thinking include a countywide testing program in Colorado and a hospital CEO in Florida who leveraged the equity in his home to buy thousands of test kits.

When Jack Michel, MD, President of **Larkin Community Hospital** (LCH) in South Miami, needed funding to buy 50,000 kits to test for COVID-19, he tapped the equity in his home to the tune of $380,000, the *Associated Press* (AP) reported. "It wasn't easy telling my wife," Michel commented.

Seeking to boost testing, LCH leased a machine from **Hologic** to run more than 1,000 COVID-19 tests per day, but

then had to wait to get approval to use the instrument. While waiting for regulatory approval, LCH sent patient specimens to **BioReference Laboratories** and got results in 48 hours, the *AP* reported. Still, LCH could not test all patients who needed testing.

Another way to increase COVID-19 testing at the hospital was to pay upfront to **Path-Tec**, a kit developer and specimen management company in Midland, Ga., for the test kits. Since the hospital's finances were already overextended, Michel paid the $380,000 himself, the *AP* wrote. With those kits in hand, LCH opened a drive-through test site in Hialeah and plans to offer more tests in the coming weeks. The hospital charges $150 per test, a price Michel said was needed to allow LCH to make more tests available.

Countywide Testing

In another example of an extraordinary measure, two executives of **United Biomedical**, a biotech company in Hauppauge, N.Y., that develops lab test kits and vaccines, will have their company pay to test all 8,000 residents of San Miguel County, Colo., for COVID-19 infections.

The executives are Mei Mei Hu, co-founder and member of the executive committee and board of directors of United Biomedical, and her husband, Lou Reese, co-founder and board member.

In addition to its offices in New York, the multinational company has operations in China, Ireland, and Taiwan. Earlier this year, United Biomedical formed a division called **c19** to develop a serologic assay called SARS-CoV-2 ELISA that detects antibodies from COVID-19 infections in human serum specimens or plasma.

On March 18, county health officials announced a partnership with c19, saying they believed the county would be the first to test all residents. The county also has a shelter-in-place order.

To identify the prevalence of the disease in Colorado's southwest corner, the county's **Department of Public Health and Environment** will administer the testing, which is voluntary. Hu and Reese have a home in the ski resort town of Telluride, which has a population of about 3,000. "This will drastically advance our ability to assess the presence of the virus in our county and allow us to focus isolation strategies," Grace Franklin, the county's Director of Public Health, said in a news release.

Retesting 14 Days Later

County officials will have healthcare providers administer the test, and they expect results within two days. Fourteen days later, they'll repeat the tests to assess whether the rate of infection has gone up or down.

The town of Vò in the Lombardy region of northern Italy completed a similar dual-testing and shelter-in-place initiative that officials credited with limiting the spread of infections there.

Hu told *The Atlantic* magazine that United Biomedical started working on an antibody test in January after the outbreak in China. The company's scientists applied what they learned from developing an ELISA test for SARS in 2004 and got blood samples from COVID-19 patients to confirm that the test detects antibodies against the virus.

Serology Tests for COVID-19

Clinical lab scientists are interested in the possibility of detecting the antibodies that result from such infections because if serological testing can find asymptomatic carriers of COVID-19, it could help health professionals understand the disease's transmission and fatality rates, the magazine reported.

On its website, United Biomedical (UB) explained that, once infected with the SARS-CoV-2 virus, the individual's immune system produces antibodies that bind to the proteins the virus generates. That process takes about eight to 10 days to produce enough antibodies for serological tests to identify in blood samples.

In Recent Days, at Least Three Companies Get EUAs for Point-of-Care and Rapid-result COVID-19 Tests

IN MARCH, the FDA granted emergency use authorizations (EUAs) to **Abbott Laboratories**, **bioMérieux**, and **Cepheid** for point-of-care or rapid-result molecular tests to identify the new coronavirus.

FDA issued the latest EUA for such a test on March 27 to Abbott for its ID NOW COVID-19 test. The assay delivers a positive result in five minutes and a negative result in 13 minutes, making it "the fastest available molecular point-of-care test for the detection of novel coronavirus," Abbott said. On Twitter, former FDA Commissioner Scott Gottlieb, MD, called it a "game changer."

Days earlier on March 20, the FDA granted an EUA for a point-of-care COVID-19 diagnostic to Cepheid for its Xpert Xpress SARS-CoV-2 test. The agency said the test could be used in high- and moderate-complexity CLIA-certified laboratories and in certain patient care settings.

The Size of a Toaster

Abbott said the ID NOW COVID-19 test is a point-of-care molecular test that physicians can use in their offices. Beginning the week of March 30, the company aims to deliver 50,000 ID NOW COVID-19 tests per day.

While speed is important, another positive feature is that the Abbott machine which runs the ID NOW tests weighs less than seven pounds and is the size of a small toaster. Therefore, it may find a home in physicians' offices or urgent care clinics.

Like Abbott, Cepheid intends to roll-out its point-of-care test right away and is aiming for March 30 as well.

The company's fully-automated molecular test is based on the design principles of the technology it uses in its current Xpert Xpress Flu/RSV cartridges to target multiple regions of the viral genome.

"The test can provide rapid detection of the new coronavirus in about 45 minutes and requires less than one minute of hands-on time for a technician to prepare the sample," the company said.

It can be used in multiple settings where actionable test results are needed to make informed treatment decisions quickly, and it delivers results with the same level of performance that reference labs produce, the company added. Cepheid has 23,000 GeneXpert Systems installed worldwide.

On March 23, bioMérieux subsidiary BioFire Defense received its EUA. The company developed the BioFire COVID-19 test with funding from the federal **Department of Defense** (DoD). While bioMérieux increases test production, the initial run of test kits is committed to the DoD for redistribution, the company said.

The test is designed for CLIA-certified moderate- and high-complexity clinical laboratories and can detect SARS-CoV-2 in about 45 minutes from a nasopharyngeal swab in transport media.

The test runs on automated platforms and requires minimal training and skills in molecular biology.

UB also said the FDA required that it provide a disclaimer to the public. The FDA has not reviewed the test and negative results do not rule out SARS-CoV-2 infection, the disclosure said, and that results from antibody testing should not be used as the only way to diagnose or exclude SARS-CoV-2 infection. "Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains and follow-up testing with a molecular diagnostic test should be considered to rule out infection," said United Biomedical. TDR

—Joseph Burns

Coronavirus Update

Labs in Italy Moved Fast to Develop COVID-19 Tests

Part One in a Series

ITALY HAS ONE OF THE WORLD'S SEVEREST OUTBREAKS OF COVID-19 INFECTIONS, based on the number of cases and the mortality rate. In response, clinical laboratories there moved quickly to launch laboratory-developed tests and to increase the volume of COVID-19 tests that they could run each day.

For Mario Plebani, MD, Professor of Clinical Biochemistry and Clinical Molecular Biology at the School of Medicine, **University of Padova**, healthcare professionals have much to learn about the virus and the steps the Italian healthcare system could have taken to respond more effectively. Plebani also is the Editor-in-Chief of *Clinical Chemistry and Laboratory Medicine* and co-Editor-in-Chief of *Diagnosis*.

"There are many things we have yet to understand about this novel coronavirus," Plebani said in an interview with THE DARK REPORT on March 25. "It was totally unexpected, which meant that our health system was not prepared." Plebani's Veneto region in northern Italy is next to Lombardy where on Feb. 20, a young man was admitted to a hospital and diagnosed with COVID-19.

"In the next 24 hours there were 36 more cases, none of whom had contact with the first patient or with anyone known to have COVID-19. This was the beginning of one of the largest and most serious clusters of COVID-19 in the world," the *Journal of the American Medical Association* reported.

"In our University Hospital, the microbiology department and my laboratory moved fast to develop a home-brew test for SARS-CoV-2," Plebani said. "This was a manual test, however, and as the number of patients needing testing increased rapidly, we started using automated tests.

"Currently we can perform about 2,500 tests daily. By next week, with new automation, we will be able to perform 3,500 COVID-19 tests daily," he added.

To date, University Hospital, where Plebani works, has not experienced problems with supply shortages. "Fortunately, personal protective equipment has been ensured up to now," he commented. "In our hospital, everyone has the masks, gloves, and other safety equipment they need. We know that the problem is increasing and are worried about having enough supplies in the future."

Drive-Up, Home Collections

When health officials noticed how quickly the virus spread among hospitalized patients, they isolated infected individuals at home and collected specimens there. "With the help of the Red Cross, we can now do home visits to collect specimens," noted Plebani. "The Red Cross also is helping to operate drive-up specimen collection centers. We want to follow this strategy to increase testing without moving patients to the hospital."

In addition to home collections, Plebani is following the development of serology tests for the virus. "As serological tests become available, it will help our labs understand more about this novel coronavirus outbreak," he explained. "These tests will help us understand how many asymptomatic subjects were infected but also stayed healthy." TDR

Contact Mario Plebani, MD, at mario.plebani@unipd.it.

Drive-Up COVID-19 Test Site Launched in 3 Days

NY Governor asks Northwell Health's lab team to help contain outbreak in Westchester County

CEO SUMMARY: After seeing the largest cluster of confirmed coronavirus infections in one location, New York State took emergency measures "to attack the hotspot at its source." The state opened a drive-through specimen-collection site offering free testing without an appointment or doctor's order. In partnership with two labs, Gov. Cuomo ordered the site be operational within three days. At one point, it was collecting more than 1,200 specimens each day.

NEVER BEFORE HAS THE NATION NEEDED DRIVE-THROUGH SPECIMEN COLLECTION to contain an infectious disease outbreak.

But on March 10, as the novel coronavirus spread quickly, New York Gov. Andrew Cuomo asked **Northwell Health Laboratories** to set up such a site in Westchester County, saying it needed to be operational three days later. Across the state, the number of positive tests for the coronavirus was rising, especially in the New York City suburb of New Rochelle. On that day, there were 173 confirmed cases statewide, including 108 cases in this community of 80,000 residents.

Cluster of Infections

To contain the cluster of infections, Cuomo announced emergency measures including a partnership with Northwell Health to establish the drive-up site in a city park. Northwell and **BioReference Laboratories** (BRLI) would do the testing.

On the recommendation of state Health Commissioner Howard Zucker, MD, Cuomo also deployed the National Guard to help manage the outbreak, and ordered the closing of schools, houses of worship, and other large gathering places.

"The largest cluster of confirmed coronavirus cases in the country is located in New Rochelle, and as the numbers continue to go up, we need a special public health strategy to contain it," Cuomo announced. "We are moving from containment to mitigation, and because much of the transmission of this disease tends to happen on a geographic basis, we are attacking this hotspot at the source."

For Christopher Zavala, Northwell Laboratory's Director of Business Development and Marketing, Cuomo's plan left him with less than three days to learn about how to run a drive-through specimen-collection site and then get it staffed and operational. In an interview with THE DARK REPORT, Zavala said those challenges were the first of several more that he and a team of phlebotomists had to overcome.

Since then, the numbers show the drive-through specimen collection operation has been a success. On the first day of operations, the Northwell team served 287 patients. Within 10 days, that volume

rose more than four-fold to 1,200 per day. As of March 26, Northwell had collected specimens from more than 8,500 patients.

"When we got the word, health system leadership said we needed five phlebotomists prepared to collect specimens at a new drive-through testing site by that Friday," he said. "We didn't have any other information about its location, the hours of operation, how to set it up, or how to run it. We also didn't know who else would be there except possibly officials from the state Department of Health (DOH).

"So, our first step was to reach out to our team of phlebotomists and ask them if they would participate," added Zavala. "We knew we could do it because we had already trained some phlebotomists about how to do the nasopharyngeal (NP) swabs.

"Still, uncertainty about how the process would work caused some reluctance among staff to volunteer," he said. "People didn't know what they were getting themselves into.

"That initial hesitation was understandable, but after they saw the operation, getting volunteers was easier because we knew this was the right thing to do," noted Zavala. "Our lab team wanted to be part of the solution. That's why we're in healthcare."

Obtaining Supplies

Once the staff was in place, the next hurdle was gathering the requisite resources, such as personal protective equipment (PPE), NP swabs, and universal transport media (UTM).

Following the example of do-it-yourselfers, Zavala searched for information about drive-through collection sites that health systems had posted on the Internet. "There are videos and pictures online—especially from South Korea and from the **University of Washington** describing drive-up testing programs," he said.

"When you're tasked to put something together so quickly, things can fall through the cracks," warned Zavala. "We wanted to make sure that we had everything possible—meaning we should at least bring what we could."

The Northwell team brought extra sets of PPE, and Zavala loaded his car with 1,000 swabs and UTM. "Just in case the people from the state DOH didn't bring those items," he said.

That Friday, at 6:30 am, Zavala arrived at the site on Glen Island Park in New Rochelle and was relieved to find that state officials brought all of the necessary equipment. What's more, the National Guard had set up traffic cones and three lanes for testing.

The site is ideal because the park is closed "due to National Guard activity," according to the city's website, and the only access is via one drawbridge from the mainland. The first day of specimen collection was scheduled to run from 7 am to 7 pm. After that first day, the hours were reset at 8 am to 8 pm. Testing continues daily.

Sample Collection Issues

The next hurdle that morning was identifying the best way to do an NP swab on a patient in a car. "In the videos, you can see that the collection itself is challenging," noted Zavala.

"An NP swab requires the patient to tilt the head back so that the collector can get the swab in far enough to get an adequate sample," he explained. "The headrest impedes a person's head when they tilt back. So, we instructed patients to lean forward and then tilt the head back."

To protect against contaminating the swab collectors, DOH officials, or the National Guardsmen who directed traffic and checked patients' identifications, state officials decided that all patients would remain in their cars with the windows closed. All communication was done through closed windows. "The National Guard also assisted patients with filling out requisitions and collecting patients' phone numbers so that the DOH could follow up with results," Zavala explained.

Once in the queue, each driver was instructed to place identification on the

dashboard so that a guardsman could check it at the first stop. No appointment is needed, but strongly recommended. Also, the testing is free, although Northwell expects the state to pay at some time in the future, Zavala said.

Collections with NP Swabs

"Originally, we thought we'd have one phlebotomist per car, meaning we'd need three phlebotomists, one for each lane," Zavala said. "But that was difficult because the phlebotomists had to instruct the drivers, do the collection, and hold the media. Therefore, it was best to have one person do the collection and one person hold the universal transport media.

"After the patients check in at the first station, they proceed to station two," he reported. "That's the hot zone where we do the actual collection."

At the second stop, the driver rolls down the window for the collector to take a specimen. Initially, the CDC required two swabs: one each in the back of the nose and throat. "About a week ago, the CDC changed their guidance so that now we just need a nasopharyngeal swab," Zavala said.

Station three is where patients check-out and get instructions about next steps and when to expect the results.

Multitasking Collectors

"When we started doing the collection, we realized it was a lot to ask of one person," he added. "Even though we work in tents, everyone is outside in the elements. And that first day it was raining and very windy.

"That made it difficult for our phlebotomists to have one hand reach into the car to do the NP swab while holding the UTM with the other hand—all while making sure they're not spilling anything or contaminating themselves," Zavala said.

"That's why we decided to have two people per car for each collection," he added. "Someone needed to assist the phlebotomist by holding the specimen and writing the patient's name on the sample. Before we started collecting specimens, we didn't realize we'd have these challenges.

"That first day we were scheduled to start at 7 am, but we didn't begin seeing patients until about 8:30 to 9 am," he reported. "We actually had some walk-ins that day and I don't know how many cars, but we collected samples from 287 patients.

"Very few people drove in by themselves," he reported. "Most cars had two people, and some cars had three or more. Sometimes there were two parents in front and three kids in the back seat because a lot of patients came with their whole families.

Van Arrives with 10 People

"I wasn't there one day when a van drove in with almost 10 people," he said. "But we couldn't swab them all because we could only reach a few through the window. The rest of them had to return at another time."

Since the first days of the operation, demand for COVID-19 tests has risen. By March 19, Northwell collected specimens from 1,200 patients—in part because state officials doubled the number of traffic lanes to six.

The 12-hour shifts made for long workdays, but the phlebotomists got breaks because Northwell scheduled four phlebotomists and four assistants for each set of three lanes of traffic, and state DOH officials provided some assistance as well, Zavala said. Also, the PPE equipment that the phlebotomists wear—which the team refers to as 'bunny suits'—includes a battery-powered ventilator to help maintain a comfortable temperature.

After the specimens are collected, they are stored onsite in a refrigerated truck. Each day, BRLI picks up the samples and then performs the testing. TDR

—Joseph Burns

Contact Christopher Zavala at 516-719-1540 or czavala@northwell.edu.

Projections based on test results show virus infections rising 10-fold every week

At the Epicenter, Northwell's COVID-19 Lab Data Adds Value

CEO SUMMARY: This intelligence briefing provides a valuable look inside a clinical laboratory that is at ground zero in a city and state that is experiencing the nation's most intense and fastest-moving incidence of COVID-19, the novel coronavirus. Lab leadership granted The Dark Report access to its strategies and how it supports health system administrators, physicians and patients, and state and local health officials. Northwell's lab team wants the lab profession to understand how the Clinical Lab 2.0 model delivers significant value and makes the lab an essential contributor during a pandemic.

During the last days of March, **Northwell Health Laboratories'** data from confirmed positive test results for the COVID-19 illness allowed lab executives to make a serious and troubling prediction.

"The prospects for the coming week or more are daunting," warned James M Crawford, MD, PhD, Northwell's Senior Vice President of Laboratory Services. "Both at the level of New York State, and at Northwell Health alone, documented COVID-19 incidence (meaning positivity, or the rate of confirmed COVID-19 tests) continues increasing at the rate of 10-fold every 13 days, even if down from every 6.5 days just the week before."

From its base in Lake Success, N.Y., just north of New York City, Northwell is in an unusually strong position to issue such warnings, because, as Crawford commented, "We are at the epicenter of the epicenter." Northwell's service area stretches from Long Island to the five boroughs of New York City and into Westchester County. Its lab test result data show that demand for testing will likely outstrip supply, he predicted.

"If unabated, our region may rapidly run out of testing capacity to document this continued increase," he said. "That means these logarithmic curves will flatten simply because we won't be able to keep up with COVID-19 testing."

In addition, lab test results support New York State's urgent demand for an increase in regional hospital beds and intensive care units. Such heavy demand is a significant concern for regional healthcare providers, especially those at the front lines, and it remains to be seen if more stringent "social distancing" practices would help to reduce this demand in the coming weeks, he warned.

By March 28, Northwell Labs had confirmed COVID-19 positivity for 9,301 Northwell patients, which represents 18% of the number of cases statewide, 7% of the number nationwide, and 1.4% of the world's total. In the United States that day, New York had the highest number of confirmed cases of the new coronavirus with 52,318, including 5,039 patients hospitalized and 728 deaths.

Unique Vantage Point

The outbreak of the virus in New York has put the clinical laboratory of Northwell Health in the center of intense efforts to document the spread of the disease and to help healthcare administrators and public health officials identify trends and design strategies to mitigate its spread. For example, on March 24, the lab projected that, without mitigation, the number of confirmed positive tests statewide for SARS-CoV-2 could race past 100,000 by the end of the month.

In recent weeks, the Northwell Laboratories have gathered test-result data under circumstances that are perhaps more challenging and intense than labs have experienced in any other region of the country. As one of the largest clinical laboratories within a health system in the United States, the Northwell Labs have an opportunity to showcase the role of a lab working under the Clinical Lab 2.0 model in delivering an unprecedented level of value by reporting real-time clinical data gleaned from lab results and delivered to health system leadership and front-line providers.

In a March 24 interview with The Dark Report, Crawford outlined the role he serves as a member of the federal **Centers for Disease Control and Prevention's** Laboratory Response Network (LRN). In this role Northwell is a sentinel laboratory, meaning it reports lab test results to the **New York State Department of Health** (NYSDOH), which forwards those results to the CDC.

"Our high COVID-19 test volume, linked with data streams from the clinical practice environment, give the health system the information it needs to guide the emergency response for prioritization of diagnostic testing, and to help inform deployment of supplies, hospital beds, ventilators, personal protective equipment, and swabs for nasopharyngeal specimen collections," commented Crawford. "By the hour—and sometimes by the minute—these lab test results are critical in the management of this crisis."

Since March 8, when Northwell Labs ran its first test for the new coronavirus, it has added new assays and instruments to increase test volume from 90 tests per day during the week of March 9 to a capacity of more than 2,000 tests each day by the third week of the

month, with further increases planned for the final days of March.

"Lab test results are among the very first starting points for managing the response to any threat, such as the coronavirus," Crawford said. "Our lab test results provide an immediate data feed to the health system, to civic authorities, and to the public. Each day, we now document COVID-19 positivity in more than 1,000 sickened patients in our regional population. And, we find that our positivity rates are now in excess of 50% of tests performed."

This intelligence briefing outlines the steps the Northwell Labs took to increase COVID-19 test volume and how data from those tests provide insight into what New York's hospitals and health systems can expect in the days and weeks to come. Clinical laboratory directors and pathologists will find the results of Northwell's efforts to date to be instructive about how clinical lab data provide insights into how hospital and health systems can manage their response to the pandemic.

Boosting Test Volume

The Dark Report previously reported on the steps Northwell followed when it validated tests for the SARS-CoV-2 virus and increased testing volume to meet an unknown level of demand. *(See "Northwell Lab Team Validates COVID-19 Test on Fast Timeline," TDR, March 9.)* Since then, the lab has added new assays and analyzers to support patient care throughout the 23 hospitals in its system.

"We now have multiple platforms running, including the CDC test for sputum, the semi-automated **GenMar**k machines—which we are deploying to our system hospitals—and additional platforms from other manufacturers," Crawford said. "Within three days of standing up the CDC assay on March 8 in the core lab, COVID-19 testing was also brought up on GenMark systems in the core lab on March 11.

"A week later, we started COVID-19 testing on March 18 using the core lab's **Hologic** Panther Fusion machines," he said. "Using the Hologic instruments allowed us to redirect the GenMark COVID-19 testing supplies to system hospitals for on-site COVID-19 testing, a step that let us use the GenMark machines already onsite in those facilities for routine respiratory virus testing.

Automating COVID-19 Tests

"Currently, we run two automated Hologic Panther machines in the core lab, and we plan to add two more Panther machines soon," he said. "We also plan to acquire other automated platforms.

"Taken together, the two Hologic Panthers and the semi-automated platforms increased our testing capacity to just shy of 3,000 results per day," Crawford explained. "That's a 30-fold increase in the 14 days since we were running 90 tests a day on March 9 using the manual CDC assay. "But now we're back to a linear rate of growth with each new Panther that we add, not logarithmic."

As soon as Northwell began running COVID-19 testing, the data analytics team of Tylis Y. Chang, MD, who heads the lab's Clinical Informatics division, could show patterns that allow Crawford and Northwell's lab team to alert physicians and other clinicians to adjust testing order priorities as conditions allow.

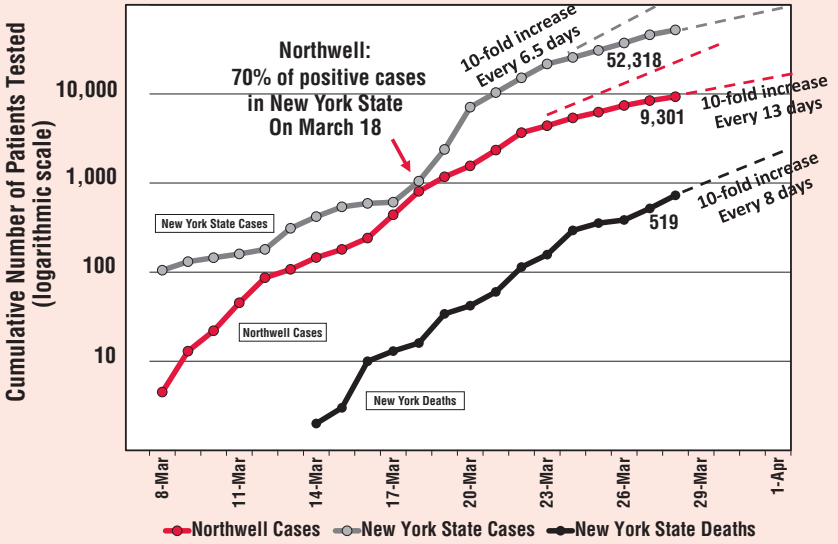
At one point, for example, blood culture testing rates rose dramatically because of the number of hospitalized patients with fever. For this reason, blood culture orders momentarily exceeded the surge capacity in Northwell's clinical microbiology lab, Crawford commented. Reporting detailed blood culture test utilization data to clinical leadership enabled quick readjustment of health system guidelines for blood culture ordering.

"We messaged strongly to our physician workforce that they should not be ordering blood cultures at the same time that they order a COVID-19 test," Crawford said in the report to staff. "Blood

COVID-19 Testing by Laboratory at Northwell Health Detects Large Proportion of Cases in New York State

Chart A: Number of Positive COVID-19 Tests, as of March 29, 2020

(showing cumulative total by day for New York State and Northwell Lab)

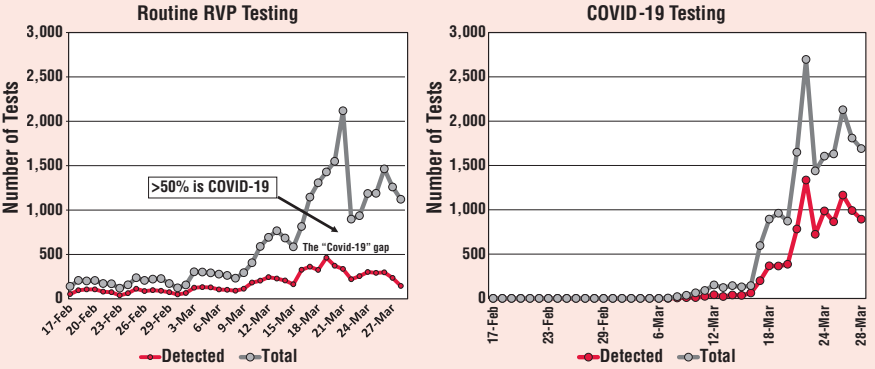


Source: James Crawford, MD, PhD, with assistance from Partha Mitra, PhD

CHART A (ABOVE): Showing the cumulative daily total of positive cases of COVID-19 for New York State and as resulted by Northwell Health Laboratories. Data show that a large proportion of positive test results in New York State are from the region served by Northwell. Cumulative state deaths also are shown.

Chart B: Comparing Positive Tests for RVP and COVID-19

(as tested daily by the Northwell Health Lab, through March 29, 2020)



Source: James Crawford, MD, PhD, with assistance from Samuel Reichberg, MD, PhD

CHART B (ABOVE): Shows how testing patients with a respiratory virus panel will miss identifying patients positive for COVID-19 and why, during this outbreak, the COVID-19 test may be the more appropriate first test that a physician should order.

cultures should be ordered when there is concern about a super-infection, such as bacteremia or sepsis."

Another alert the lab sent to physicians and lab personnel addressed the shortage in nasal swabs for specimen collection. "We instructed that one swab is sufficient for testing both the rapid respiratory virus panel (the RVP from GenMark) and COVID-19 polymerase chain reaction (PCR) test," he explained. "These real-time adjustments in health system management of COVID-19 patients were essential for ensuring that our health system could optimize use of both laboratory and system resources."

Many hospitals and health systems are running the RVP first to identify patients who have flu-like symptoms but may not have the novel coronavirus. Before the Hologic Panthers went live, Northwell took the opposite approach.

"We stated that when a patient is suspected of having COVID-19 and when test positivity rates in hospitalized patients exceed 50%, ordering the COVID-19 PCR test first was preferable," Crawford reported to staff. "The Rapid RVP could follow if the COVID-19 PCR test was negative.

"Now that COVID-19 testing is being pushed out to system hospital sites the same concern applies because routine Rapid RVP testing takes up local capacity for COVID-19 PCR testing on our semi-automated machines.

"That said, we constantly adjust our testing recommendations," he commented. "When core lab testing capacity expanded, we could then run the Rapid RVP and COVID-19 tests on different platforms, meaning both tests could be ordered and resulted again without canceling any tests. We monitor such load-balancing daily and have constant communication among clinical leadership about test ordering recommendations."

One important way that lab test result data are used is to understand the epidemiology of how the virus spreads. "Since March 1, the lab test results we're reporting have been pushed out into the community to inform public health activities," Crawford commented. "The first confirmed case in New York was March 1, through public health laboratory testing.

SARS CoV-2 Assay

"One week later, the Northwell lab was ready to run its CDC assay for SARS-CoV-2," he added. "On Sunday, March 8, our lab reported its first positive test result from the Northwell Health system.

"At our lab's command meeting the next morning, we activated our Laboratory Incident Command, reporting up to the health system Incident Command," noted Crawford. "As our 10-person laboratory command group divvied up these tasks, I took on the responsibility for laboratory-driven epidemiologic reporting.

"Once you test people who are symptomatic, that data can guide how the health system responds to care for the most critically-ill patients," he said. "We hope the day will come when we can provide testing for a broader portion of our regional population. But for the time being, our testing is for the patients with the greatest need-to-know, whether they are COVID-19 positive or not.

Analyzing Lab Data

"We are doing health services research by linking the test results from symptomatic patients with clinical, demographic, and geographic information," he added. "For example, we want to identify the indications for repeat testing. We also want to identify patients who convert from negative to positive and what it means when they convert in that way. We have some interesting leads, but we're not ready to publish them yet.

"Also, we found that the rate of patient tests that are positive for the new coronavirus varies depending on the clinical site ordering the test," he said. "If the COVID-19 test originates from one of our hospitals

Boosting the Number of COVID-19 Tests the Laboratory Could Perform Required Multiple Steps, Automation

SINCE THE NOVEL CORONAVIRUS WAS IDENTIFIED AT THE END OF LAST YEAR, all clinical laboratories have faced the challenge of determining the fastest and most effective ways to meet an unknown level of testing demand.

At **Northwell Laboratories**, Stefan Juretschko, PhD, D(ABMM), Northwell's Senior Director of the Division of Infectious Disease Diagnostics, has led the lab's efforts to increase capacity to test for the virus that causes the COVID-19 illness.

On March 8, the lab resulted its first run of COVID-19 clinical tests, after having worked with the New York State Department of Health over the prior three days to validate the test kit from the federal **Centers for Disease Control and Prevention** (CDC), according to James M. Crawford, MD, PhD, Northwell Health's Senior Vice President of Laboratory Services.

Juretschko's lab completed validating the test on Saturday, March 7. That evening, he submitted to the state the data needed to support the lab's request for emergency use authorization (EUA), under the FDA guidelines. The state approved Northwell's request and the lab proceeded with the CDC assay the next day, Sunday, March 8. On that first day of testing, the lab ran nine of the manual COVID-19 tests. During the next three days, the lab ran about 90 such tests per day for the highest priority patients at Northwell Health system.

On March 11, the state gave Juretschko approval for the core lab to go-live with a semi-automated qualitative multiplex assay to detect SARS-CoV-2 nucleic acid from specimens collected from nasopharyngeal swabs. That test from **GenMark Diagnostics** runs on GenMark's ePlex Sample-to-Answer System. Using that test, Northwell boosted coronavirus test volume to about 150 to 200 tests each day, Crawford reported.

Juretschko went live on March 18 with a fully automated assay from **Hologic** (the Panther Fusion SARS-CoV-2 test), which detects genetic material from the virus in less than three hours. The FDA approved Hologic's EUA for that test on March 16. Using two Hologic Panther machines allowed Northwell to run more than 2,000 tests per day.

(meaning an emergency department, inpatient admission, or intensive care), the test positivity rate is now almost 70%.

"By comparison, if the test comes from one of our urgent care centers, the positivity rate is 57%, and if it is from a physicians' office, the rate of positivity is 48%," Crawford explained. "What this means for physicians treating symptomatic hospital-based patients is that their illness is caused by COVID-19 until the laboratory test indicates otherwise.

"Although the probability of a positive result is lower if a patient presents at an urgent care center or in a physician's office, at this time, each of those sites still has a staggeringly high positivity rate in our regional population," he added.

"To me, these are incredible numbers that document the penetration of the virus into our community," he reported. "In addition, when we combine our COVID-19 test results with results from the tests we do with our routine respiratory virus panel, we see a trend in that data that helps us know what we can expect in the coming weeks."

Predictive Value of Results

From their position in clinical informatics, Chang and Samuel Reichberg, MD, PhD, a pathologist and informaticist, have shown that—since March 6—the many patients who are symptomatic for the flu and are tested using the Rapid RVP get a negative test result over 80% of the time. In other words, these patients do not have any of

the 14 respiratory virus types or subtypes that the GenMark panel identifies and yet they have flu-like symptoms. "That means that the many patients who get the Rapid RVP test and a negative result are a lead indicator of entry of the new coronavirus into our population," Crawford observed.

Charting RVP, COVID-19

Reichberg showed this pattern by creating a chart showing the number of positive tests with the Rapid RVP panel against the total number of RVP tests performed, noted Crawford. "The gap between positive and negative tests was an indication of the presence of COVID-19," he said. That data showed RVP results from Feb. 17 through March 29. *(See sidebar on page 17, "COVID-19 Testing by Laboratory at Northwell Health Detects Large Proportion of Cases in New York State.")*

"We call the difference between the RVP positive tests and the total tests the COVID-19 Gap," Crawford explained. "That gap is significant because that's where the coronavirus lives before it's detected with the SARS-CoV-2 test."

After Northwell Lab's first testing for COVID-19 on March 8, the gap widened considerably, an indication that some patients who had tested negative with the RVP were in high likelihood positive for the SARS-CoV-2 virus, he said.

Negative Results

"Beginning after March 8, the number of completed COVID-19 tests in our lab began to rise," he noted. "On about March 10, physicians also ordered more tests using the RVP. Yet results for the vast majority of their patients came up negative.

"The chart (on page 17) shows that on March 13, there are 500 or so symptomatic patients who were tested using the RVP and yet those tests were negative, versus about 100 patients who tested positive," explained Crawford. "That's a five-fold increase in negatives.

"A few days later, on March 17, about 700 symptomatic patients were tested with the RVP and those tests were negative and again there were about 100 cases of flu that the RVP detects," he said. "That's a seven-fold increase in the number of RVP tests that were negative.

"These increased test volumes were a sign that something was happening because physicians were testing patients who had flu-like symptoms, but the RVP tests were negative," he noted. "This was a lead indication of a new respiratory illness, which Northwell had been expecting."

Lab Data Reporting

The Northwell lab team reported these findings to the health system and to ordering physicians, Crawford said. "To create the data to track the epidemiology of the disease, we put a lot of work into analyzing changes in both the volume and results of RVP tests, and the rapidly-emerging COVID-19 positive test results," Crawford reported.

"To do that, we assembled a team of six people in the laboratory to crunch the numbers for the lab," he continued. "We were essentially on a 24-hour cycle. In addition, we were working with dozens of data scientists at the system level in our health services research department.

"These numbers show how the disease spread over a four-week period, and we disseminate these data as quickly as possible so that we can guide our practice community and our health system administrators about what's going on with this disease outbreak," noted Crawford.

"Also, I've sent these data to my national peer group of academic pathology chairs to help them prepare for what's coming their way," he reported. "Basically we're talking about urgent, real-time lab data science. Every day, we demonstrate the value of lab data that we can track, analyze, and disseminate.

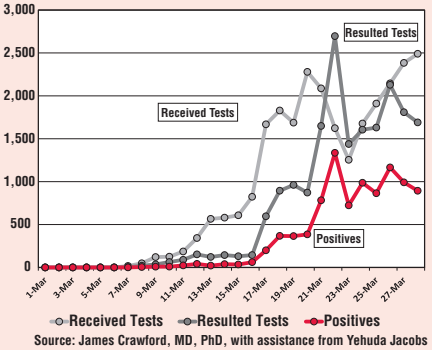
"We've spent the last four years developing our skills as Clinical Lab 2.0 providers, and, in many ways, this is the

Even as Volume of COVID-19 Tests Increases, Growth in Percent of Positive Results Continues

Daily Resulted COVID-19 Tests and Daily Positive COVID-19 Tests

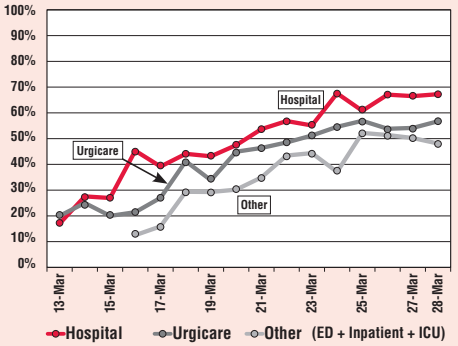
(for Northwell Health Laboratory, through March 29, 2020)

Northwell: Daily Resulted COVID-19 Tests



Source: James Crawford, MD, PhD, with assistance from Yehuda Jacobs

Northwell: COVID-19 Daily Positivity Rates

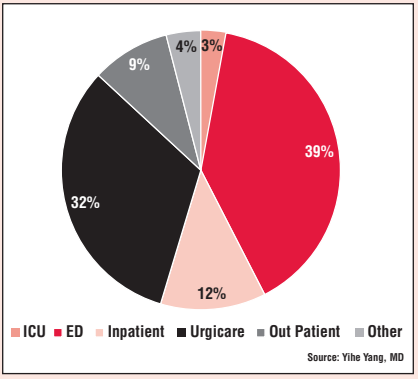


CHARTS ABOVE: Chart at left shows the Northwell Lab's number of COVID-19 tests received, the number of test results, and the number of positive results. Chart at right shows the percent of daily COVID-19 positive results by site, including hospital (ED + Inpatient + ICU), Urgent Care, and other. Over the two-week period shown, the percentage of positive results increased to a range of 50% to 60%.

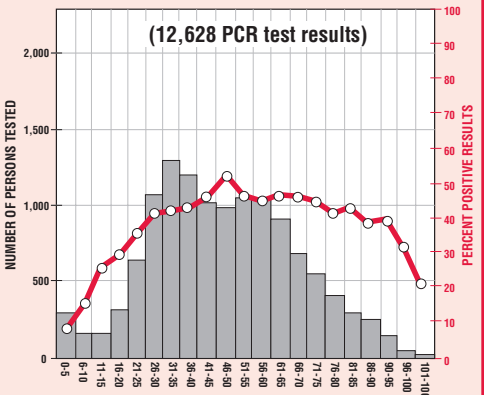
Source of COVID-19 Tests and Positivity Rates by Age Groups

(for Northwell Health Laboratory, through March 29, 2020)

Cumulative Resulted Tests by Clinical Site



Age and % positivity: SARS-CoV-2



CHARTS ABOVE: Pie chart at left shows the clinical settings that referred COVID-19 tests. Urgent care (32%) and emergency department (39%) represent 71% of total COVID-19 tests. Bar chart at right shows cumulative COVID-19 positive test results for different age groups. The range is basically from a low of 20% to a high of over 50%.

new religion with our laboratory," concluded Crawford. "Given the extraordinary events that are happening now, our provider community and our health system leadership need no convincing of the value of Northwell Labs as their laboratory provider." TDR

—Joseph Burns

Contact James M. Crawford, MD, PhD, at 516-719-1060 or jcrawford1@northwell.edu.

In NY, Lab Offers Mobile Virus Sample Collections

➤Phlebotomists trained in use of NP swabs collect COVID-19 specimens at residences of certain patients

➤➤CEO SUMMARY: To allow patients and physicians to order at-home specimen collections of the novel coronavirus, Northwell Labs trained its 12-member mobile phlebotomy service in the procedures needed to collect samples using nasopharyngeal (NP) swabs. Since training occurred in the second week of March, demand has increased steadily from one to two calls per day to five to 10 requests daily. Collecting COVID-19 specimens from patients at their residences helps limit exposure to the virus.

Clinical laboratories offering mobile phlebotomy services are now an important resource to increase testing for home-bound and nursing home patients to help slow the outbreak of the novel coronavirus.

Providers can order a mobile nasopharyngeal specimen collection for their patients so they can remain at home, reducing the possibility of spreading the pathogen by seeking a test from a doctor's office, emergency room, or urgent care center. Knowing that waiting rooms present infection risks, physicians have been limiting office visits.

In response to these problems, **Northwell Laboratories** in Lake Success, N.Y., has adapted its mobile phlebotomy service, called LabFly, for patients who need testing for the novel coronavirus. During the early stages of the COVID-19 outbreak, the lab team trained its 12-person staff of mobile phlebotomists to collect the specimens via nasopharyngeal (NP) swab for symptomatic patients who meet certain criteria, said Michael Eller, the lab's Assistant Vice President of Business Development and Strategy.

When the service began during the week of March 9 to 13, the team got one to two calls for nasal swab collections per day, said Bryan Hemmings, Northwell's Senior Director for phlebotomy. As of March 27, the team was fielding five to 10 calls each day, he said.

➤Testing Criteria

"Currently, we're limiting the mobile specimen collection service to patients who meet defined criteria to be tested or those in a nursing home or other facility who have symptoms or who have a physician's or health department referral," Eller explained. The service operates on weekdays from 7 am to 5 pm and occasionally later into the evenings and sometimes on weekends if needed.

After the phlebotomist collects the specimen, the patients remain at home while the specimen is tested, reducing the risk of spreading the disease.

The mobile specimen collection is one of two innovative strategies Northwell Labs has developed in response to the pandemic. The other strategy is a drive-through specimen-collection facility

that Northwell and the **New York State Department of Health** opened March 13 in Westchester County, N.Y. *(See "Drive-Up COVID-19 Test Site Launched in Three Days," page 11.)*

Since 2010, the lab has run a mobile phlebotomy service for nursing home and home-bound patients. Last year, Northwell expanded the service to all patients needing bloodwork by developing a mobile-phone app called LabFly that patients can use to schedule a blood collection at home or the office. For this service, Northwell charges each patient a fee of $19.99. Insurance usually pays for the testing. *(See, "COVID-19 Patient? Northwell Has Mobile Phlebotomy App," TDR, March 9, 2020.)*

"Because this staff for this service was already mobilized on the road, it was a perfect vehicle for getting patients' COVID-19 swabs collected at home," Eller commented.

Partnering with EMS

When the virus began to spread worldwide, Northwell Laboratories recognized the opportunity to have the LabFly mobile phlebotomy team learn to do NP swabs, Hemmings said.

To train phlebotomists to do NP swabs, the lab team partnered with Northwell Health's emergency medical service (EMS) unit. The EMS doctors and the lab's pathologists instructed the phlebotomists and emergency medical technicians how to collect the specimens and how to use the personal protection equipment (PPE) in patients' homes. Learning how to don and doff PPE is an essential skill for medical professionals because doing so incorrectly can spread the virus.

To protect the phlebotomists from being exposed to the new coronavirus while serving patients, the laboratory developed a protocol for the best time and place to put on the PPE mask, gown, and gloves. As news reports show, healthcare professionals seeking to remain free of COVID-19 need to know the proper procedure for using PPE, known informally as "bunny suits."

"We also had EMS train the trainers so that we can add staff as demand and testing capacity increases," Hemmings added.

For Home Visits, Lab Sets Process for Donning PPE

WHEN DEPLOYING PHLEBOTOMISTS TO DO NASOPHARYNGEAL (NP) SWABS, Northwell Health's lab team needed to determine the best time and place to don the personal protective equipment (PPE) the specimen collectors need.

Northwell Lab's mobile phlebotomists are trained to do NP swabs, and they use their personal cars to drive from one call to the next. At the start of each day, the phlebotomists collect the swabs, universal transport media, and the PPE they'll need for each NP-swab collection. In that way, they can do phlebotomy calls as they usually do and collect with NP swabs if needed.

Bryan Hemmings, Northwell's Senior Director for phlebotomy, recognized that having phlebotomists put on the PPE suits before going into a patient's home could be problematic. Doing so could give away information about the patient's health and draw unwanted attention to the patient and the phlebotomist.

"We don't want people putting on the PPEs in the street," Hemmings commented. "Doing that could get the neighbors worked up or frightened. Instead, when the phlebotomist arrives, we asked them to call the patient by phone.

"Once the patient comes to the door and before the phlebotomist goes into the house, we ask them to put on the face mask," he added. "Once they put the mask on, they step inside the house and then put on the gown and gloves."

One challenge Eller and Hemmings faced was establishing criteria for responding to requests for collecting virus specimens. "We set the policy to do at-home collections for patients who suspect they have the coronavirus on an as-needed basis," Hemmings explained. "Due to limited testing capacity, we didn't advertise the at-home service because we didn't want to get overwhelmed with requests."

Physician Referral Needed

To qualify for an at-home collection, the lab team decided that patients would need to be symptomatic or have a referral from a physician or from the state or a county department of health.

"When patients or family members request at-home specimen collections, we take steps to qualify them," Hemmings said. "We want to know if the patient has seen a doctor or has symptoms."

While patients who need a blood draw can use the LabFly mobile app to request and pay for a phlebotomist for a blood draw at home, patients cannot use the LabFly app for an NP specimen collection—at least not now, Hemmings and Eller said.

The app also allows the lab team to track phlebotomists' locations throughout the workday. "That function makes it easy for us to send phlebotomists to do NP swabs if they're close by when a physician requests it," Hemmings said. This feature is important given that Northwell Health's service area stretches from the eastern end of Long Island into the five boroughs of New York City and to the city's northern suburbs in Westchester County.

Another problem for the lab team involved the logistics and timing of getting the specimens back to the lab. "We try to have a four-hour turnaround time, meaning from the time a patient or doctor requests a mobile specimen collection until the specimen arrives at the lab," Hemmings reported.

"We do that by having phlebotomists drop specimens at the patient service centers we have in Queens and Long Island," he added.

Few mobile phlebotomy companies are collecting patient specimens for testing for the novel coronavirus. One that is doing such mobile collections is **VeniExpress**, a company in San Diego that serves physician offices, home health agencies, and hospice providers.

VeniExpress is partnering with several local laboratories to service their patients who want or need to have their blood drawn or specimens professionally collected in their homes.

"As the coronavirus spreads throughout the United States, many people have legitimate concerns about leaving their homes, even for vital services such as blood draws," the company explained.

On the other hand, **Apex Laboratory**, a company in Westchester County, Elmsford, N.Y., which offers a mobile phlebotomy service, would not collect specimens from patients who have been diagnosed with the COVID-19 illness or have any of the known symptoms, the company said on its website.

Patients with COVID-19

"Please notify Apex immediately if your patient tested positive for COVID-19 or is a person under investigation for the COVID-19 illness," said the company. Also, Apex would not test a person who lives in a community where community-based transmission of coronavirus is occurring.

Apex would not collect from a person who tested positive for the virus and is under mandatory quarantine or has had the symptoms of a respiratory infection, such as a fever, cough, shortness of breath or sore throat and has had contact with someone with a confirmed or suspicious diagnosis of Coronavirus in the past 14 days, the company said. TDR

—Joseph Burns

Contact Michael Eller at 516-286-3292 or meller@northwell.edu; Bryan Hemmings at 516-286-9983 or bhemming@northwell.edu.

Lab Compliance Update

Regulators Acted Slowly as Labs Developed Tests for Coronavirus

Amid early outbreak in Seattle, officials shut down one research lab's test for SARS-CoV-2 virus

When the first deaths from the novel coronavirus were reported in Seattle beginning on Feb. 29, Helen Chu, MD, MPH, took notice. An infectious disease expert at the **University of Washington School of Medicine**, Chu is a director with the **Seattle Flu Study**. Since late last year, researchers for the study have collected 2,500 flu samples from Seattle residents.

On Feb. 25, Chu and her colleagues at the Seattle Flu Study started testing patients for the SARS-CoV-2 virus that causes the COVID-19 illness, but just over one week later, state regulators told Chu and her colleagues on March 9 to stop testing to identify patients with coronavirus infections, *The New York Times* reported. The laboratory was not CLIA-certified, as other publications explained.

Also, the flu study should not be repurposed to test for the coronavirus, the *Times* wrote, because it was a research project that lacked the requisite permission from the research subjects. "While acknowledging the ethical questions, Dr. Chu and others argued there should be more flexibility in an emergency during which so many lives could be lost," the *Times* added.

The reporting in the *Times* and elsewhere on Chu's efforts to develop a test to identify COVID-19 in patients became fodder for a debate about harms of over-regulation of testing in this setting.

"What should have been allowed was for the research study to continue testing for the flu while a CLIA-certified lab, such as the University of Washington, could use the flu study's test to identify patients with coronavirus," explained Roger D. Klein, MD, JD, a former adviser to the FDA and a faculty fellow at the **Center for Law, Science and Innovation** at the **Sandra Day O'Connor School of Law**.

As the *Times* explained, Chu and a team of researchers asked state and federal officials for permission to repurpose the study's flu test to identify the coronavirus but were denied. Despite the denial, the researchers began performing the coronavirus test on Feb. 25 without government approval, the *Times* reported.

Laboratory Regulation

Pathologists and clinical lab directors will recognize the issue, because as Klein explained, the lab was not CLIA-certified and therefore was violating federal law by testing patients for clinical purposes. "There are good reasons to have regulatory oversight of clinical testing, but research studies fall outside this framework," he added. "Although conceptually this is a form of regulation, the basis is a Congressionally-enacted statute.

"The *Times* conflated or confused regulations governing clinical laboratories with regulations governing a research lab," he said in an interview with THE DARK REPORT. "The two kinds of labs are very different entities. It was disappointing that the coverage didn't provide greater clarification on those differences."

While the distinction between regulation of research and clinical lab testing

was an issue in the Seattle case, there was another issue related to regulation—or in this case, overregulation of lab-developed tests—that caused needless delays in testing nationwide, Klein charged.

"The **FDA's** prohibition against LDTs that academic medical centers, community hospitals, and health systems could have used to test for COVID-19 harmed our capacity to address the outbreak," he said. "The prohibition potentially contributed to the deaths in Washington State and elsewhere and impaired our ability to recognize the extent to which community spread of SARS-CoV-2 had occurred.

"That action stands in stark contrast to what happened during the H1N1 epidemic in 2009, when hospital laboratories set up their own tests," Klein added. "Those labs responded rapidly, and that fast action provided important information for both patient management and epidemiologic use."

In an op-ed Klein wrote for *City Journal*, which the **Manhattan Institute** publishes, Klein wrote, "It's troubling that community spread of the novel coronavirus in Washington State and other parts of the United States—possibly affecting hundreds to thousands of individuals—wasn't detected sooner.

"Overregulation of diagnostic testing has played a major role in this delay," he added. "For weeks, the **CDC** operated the nation's sole diagnostic laboratory for coronavirus, while testing in the rest of the world proceeded apace."

PCR Protocols Published

As we reported, researchers in China published protocols in January to use polymerase chain reaction (PCR) to test for the virus. *(See "Northwell Lab Team Validates COVID-19 Test on Fast Timeline," TDR, March 9, 2020.)*

Since early February, the **World Health Organization** (WHO) has shipped more than 250,000 tests to 159 laboratories worldwide after replicating a procedure developed in a lab in Berlin, Germany, to create a test kit, Klein explained.

On March 11, *Bloomberg Businessweek* reported that the German lab, **TIB Molbiol Syntheselabor GmbH**, produced 40,000 coronavirus diagnostic kits—enough for about four million individual tests. The kits sell for €160 (or $180) and orders poured in from WHO, national health authorities, and laboratories in 60 countries, tripling the lab's revenue in February over what it reported for the same month last year.

In China, health authorities approved 10 different manufacturers' test kits by Feb. 23 to boost weekly production capacity to 1.65 million tests, Klein wrote in his op-ed. "Meantime, South Korea has more than 500 testing sites reportedly testing 10,000 individuals per day."

A Slow Response

In contrast, according to the CDC, labs in the US had performed only 472 tests by March 2, he added. "Historically, FDA regulation has been confined to manufactured and distributed test kits," he commented. "The agency has had little to no role in regulating clinical laboratories or the tests they develop and implement.

"CLIA-certified labs have significant oversight," he commented. "They're not regulated by FDA and we don't have evidence of widespread or systemic problems from the tests these labs introduce.

"The FDA should have continued the policy it pursued during the H1N1 outbreak in 2009, Klein said. In 2014, the FDA set forth a framework for regulating LDTs in proposed guidance that was withdrawn after the November 2016 elections. The previous March, the FDA sent warning letters to labs that developed assays during the Zika outbreak in 2016. *(See, "At FDA, Laboratory-Developed Tests Are in the Crosshairs," TDR, March 21, 2016.)*

—Joseph Burns

Contact Roger D. Klein, MD, JD, at 203-927-0257 or roger@rogerdklein.com.

INTELLIGENCE

LATE & LATENT

Items too late to print, too early to report

Should consumers be allowed to collect their own specimens for a COVID-19 test? At least five companies announced plans in mid-March to sell COVID-19 tests directly to consumers and have them collect their specimens at home, then return the samples to the the labs doing the testing. This scheme came to a quick end, however, on March 20 when the federal **Food and Drug Administration** (FDA) issued an alert to consumers to be aware of, among other things, "unauthorized, fraudulent COVID-19 kits." The next day, the FDA updated its website's FAQ for diagnostic testing and expressly stated that "the policies outlined in the Policy for Diagnostic Tests for Coronavirus Disease-2019 do not apply to at-home testing, including self-collection of samples to be sent to a clinical laboratory."

MORE ON: *Consumer Tests for COVID-19*

In the days preceding the FDA's clarification on consumer self-collection of samples for COVID-19 tests, at least five companies had issued public statements that they were offering COVID-19 tests for consumers. These companies were **Carbon Health**, **Everlywell**, **myLAB Box**, **Nurx** and its laboratory partner **Molecular Testing Labs**, and **Scanwell Health**. The FDA's swift action on this COVID-19 test issue may be a reaction to the sustained criticism from clinical laboratory professionals, the news media, and others about how the agency was slow to expedite the process CLIA-certified clinical laboratories must use to meet regulatory requirements for developing and validating COVID-19 tests intended for use in patient care.

MIGHT SARS-COV-2 CHANGE HOW LDTS ARE REGULATED?

One unresolved issue in the clinical laboratory industry is FDA regulation of laboratory-developed tests (LDTs). Clinical labs, *in vitro* diagnostic (IVD) companies, and others regularly challenge efforts by FDA officials to expand their agency's regulation of LDTs. The current outbreak of the novel coronavirus is getting the full attention of the public, the news media, and Congress. Once the current COVID-19 outbreak subsides, all sides may view LDT regulation very differently, and in ways that might lead to a consensus on how LDTs should be regulated.

TRANSITIONS

• Pathologist Stephen Schwartz, MD, PhD, 78, a Professor of Pathology at the **University of Washington** in Seattle, died of COVID-19 on March 17, after being admitted to the hospital for that disease. Schwartz joined UW 54 years ago, in 1967, as a pathology resident and became an assistant professor in 1973.

That's all the insider intelligence for this report. Look for the next briefing on Monday, April 20, 2020.

Share Your Laboratory's Innovations in Responding to the COVID-19 Pandemic and Helping Physicians, Patients

CALL FOR LAB SUCCESS STORIES!

During this COVID-19 pandemic, clinical labs across the nation are stepping up to serve their hospitals, physicians, and patients in innovative ways. Labs are dealing with issues that have no precedent!

Never before has a new infectious disease caused such worldwide disruption to normal social interaction and economic activity. At the same time, increasing transmission of the SARS-CoV-2 virus threatens to overwhelm hospitals and other healthcare resources.

This makes it imperative that clinical labs share their lessons in the new and creative ways they are using lab tests and lab test data to help providers mitigate the outbreak and diagnose patients earlier and more accurately. The Dark Report and DarkDaily.com are ready to gather and share this knowledge with the clinical laboratory profession. Please reach out to our editorial team in confidence.

To share your lab's innovations and successes, contact our Editor at: rmichel@darkreport.com

UPCOMING...

- ***North Shore Health's Lab Team Acts Early to Develop CDC COVID-19 Test, Get it Automated, and Build Test Volume.***
- ***Next Financial Crisis for Many Labs: Lost Revenue Because Patients Are Not Visiting Their Doctors During the Pandemic.***
- ***Can Clinical Labs and Pathology Groups Benefit from the New $2.2 Trillion Coronavirus Economic Rescue Bill?***

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