Celebrating 15 Years

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LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

UHC Hits Texas Pathologists With ~50% Rate Cuts

Starting in February, UnitedHealthcare began to notify pathology practices in Texas that it was revising its reimbursement rates for anatomic pathology paid under long-standing "legacy" contracts. For some Texas pathologists, UHC's new rate schedule has resulted in reductions of roughly 50% for key professional and technical codes.

In letters to Texas pathologists, UHC said it was updating its commercial fee schedule reimbursement based on 2019 Medicare RVUs. This means that Texas pathology groups with legacy contracts based on Medicare rates from 10 or even 20 years ago will see substantial reductions that reflect the more recent Medicare rate cuts to CPT 88305 and 88342, notes Ann Lambrix, Vice President of Client Services at Vachette Pathology (Sylvania, OH). *Continued on page 9.*

Progenity Raises $100 Million From IPO

Progenity Inc. (San Diego, CA) raised gross proceeds of $100 million through an initial public offering (IPO) of 6.667 million shares priced at $15 per share on June 19. Underwriters of the offering were Piper Sandler, Wells Fargo Securities, Robert W. Baird, Raymond James and BTIG. Net proceeds to Progenity were approximately $89 million, after deducting underwriting commissions and IPO expenses. Progenity operates a CLIA-certified lab in Ann Arbor, Michigan, that specializes in noninvasive prenatal testing (NIPT) to determine the risk that a baby will be born with certain genetic abnormalities.
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Quest Diagnostics To Take 100% Stake In Mid America Clinical Laboratories

Quest Diagnostics has reached a deal to acquire the 47% remaining interest in Mid America Clinical Laboratories (MACL-Indianapolis, IN) that it doesn't already own. MACL is a joint venture owned by Quest (53% stake), Ascension St. Vincent (25%) and Community Health Network (22%) with 750 employees, 50 patient service centers and more than $100 million in annual revenue. Quest will become the sole owner of MACL when the deal is complete (expected by Sept. 30).
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Quest Diagnostics To Take 100% Stake In MACL (*cont'd from page 1*)

Quest says it will operate and manage approximately 30 hospital labs for the two health systems under separate professional lab services agreements.

MACL's main laboratory is located in Indianapolis. At least some test volume is expected to transition to Quest's regional lab in Wood Dale, Illinois.

The MACL joint venture laboratory was originally formed in April 1997 by SmithKline Beecham Clinical Laboratories (SBCL-44% stake), St. Vincent (25%), Community Health (22%) and a local pathology group named CoLab (9%). CoLab was acquired by AmeriPath in late 1997. Quest acquired SBCL in 1999 and then AmeriPath in 2007 to obtain its current 53% stake in MACL.

The latest available annual report from Community Health shows that MACL earned net income of $13.4 million on revenue of $124.2 million in 2018.

Mid America Clinical Laboratories Financial Summary ($ 000)

	2018	2017	2016	2015	2014	2013	5-year CAGR
Total revenue	$124,240	$120,721	$118,183	$117,508	$111,830	$108,905	2.7%
Operating Income	13,359	13,832	14,037	14,408	12,528	12,475	1.4%
Net Income	13,442	13,814	14,032	14,424	12,513	12,493	1.5%
Total assets	44,974	45,778	44,631	51,457	48,642	44,535	0.2%
Total liabilities	8,180	6,639	8,668	11,454	12,782	13,571	-9.6%
Net assets	36,794	39,139	35,963	40,003	35,860	30,964	3.5%
Medicare Part B revenue	NA	8,328	8,064	8,146	7,498	7,522	NA
Medicare Part B test volume	NA	623,267	616,262	630,312	594,828	594,528	NA
Avg. Part B revenue per test	NA	13.36	13.09	12.92	12.61	12.65	NA

Source: Community Health Network annual reports and CMS

Other joint venture lab companies where Quest has ownership stakes include Diagnostic Laboratory of Oklahoma LLC (51% stake), Quest Diagnostics Venture LLC in Pittsburgh (51%), Associated Clinical Laboratories in Erie, Pennsylvania (53.5%), Sonora Quest Laboratories LLC in Arizona (49%) and Quest Diagnostics Massachusetts LLC (81%).

BioReference Wins Lab Contract With Westchester Medical Center

OPKO's BioReference Laboratories (Elmwood Park, NJ) has signed a long-term service contract with the Westchester Medical Center Health Network (Valhalla, NY) to provide inpatient lab administrative services, reference testing and outreach testing services.

WMCHealth has 10 hospitals on eight campuses across the Hudson Valley Region of New York, including Westchester Medical Center (885 beds) and MidHudson Regional Hospital (243 beds). Altogether, WMCHealth has an annual laboratory department budget of approximately $65 million and performs over seven million lab tests per year.

Under the agreement, BioReference will provide inpatient lab administrative services and purchasing management services for lab equipment and supplies initially for Westchester Medical

Center. In addition, BioReference's main lab in northern New Jersey will become the primary reference lab and perform clinical lab outreach testing for the entire hospital network. The agreement does not involve anatomic pathology services.

Jon Cohen, MD, Executive Chairman at BioReference, expects the company to sign similar agreements with other health systems in the future.

Top 5 WMCHealth Hospitals, 2018

Facility Name	Location	Total Staffed Beds	Total Laboratory Department Cost*
Westchester Medical Center	Valhalla, NY	885	$50,427,539
MidHudson Regional Hospital	Poughkeepsie, NY	243	6,865,029
HealthAlliance - Broadway Campus	Kingston, NY	149	4,224,926
HealthAlliance Hospital Mary's Ave. Campus	Kingston, NY	105	2,016,225
Margaretville Memorial Hospital	Margaretville, NY	97	1,330,747
Total		1,479	$64,864,466

*Includes operating expenses and overhead allocations

Source: American Hospital Directory and Hospital Cost Reports

Majority Of NYC Nursing Home Employees Have Had Covid-19

BioReference Labs reports that Covid-19 antibody testing it performed on nursing home employees throughout New York State in May-June showed a 29% positivity rate. New York City nursing home employees were found to have the highest positivity rate (55%).

During the same time period, BioReference performed PCR-based molecular tests for active Covid-19 infection and found a 2.9% positive rate throughout the state, including a 4.6% positive rate for New York City nursing home employees.

The testing was performed as a result of a New York State mandate (effective May 10) that all personnel at nursing home and adult care facilities be tested for active Covid-19 infection using PCR-based molecular testing, twice per week. In addition, at the start of the program, many nursing homes asked that employees be tested for antibodies at the same time.

BioReference uses the Roche Elecsys Anti-Sars CoV-2 assay for antibody testing. Overall, BioReference tested 3,488 nursing home employees in New York State (primarily in May) for antibodies and found 1,010 positive cases. "With 29% of employees testing positive for antibodies, an extrapolated estimate for the 140,000 total nursing home staff in New York State suggests as many as 41,760 nursing home staff members in the state could have had Covid-19 prior to early May," according to Jon Cohen, MD, Executive Chairman at BioReference.

Covid-19 Test Results for New York Nursing Home Employees (May-June 2020)

NY Region	Antibody % Positive	PCR-Based % Positive
New York City	55.1%	4.6%
Westchester/Rockland	37.1%	3.1%
Long Island	35.4%	1.2%
Upstate	16.2%	2.2%
Statewide	29.0%	2.9%

Source: BioReference Labs

Progenity Raises $100 Million From IPO (*cont'd from page 1*)

Progenity's test brands include Innatal Prenatal Screen: a blood test for women early in pregnancy that screens for risk of fetal chromosomal conditions, such as Down syndrome (Trisomy 21), Edwards syndrome (Trisomy 18) and Patau syndrome (Trisomy 13). Progenity markets the test through a direct sales force of 140 reps that call on OB/GYN offices. The CPT code is 81420 with a Medicare CLFS rate of $759. Primary competitors include Invitae, Myriad Genetics/Counsyl and Natera.

Other proprietary tests marketed by Progenity include Preparent Carrier Test, an expanded carrier screen that is performed on women or couples before conception; Riscover Hereditary Cancer Test, a hereditary cancer screen; and Resura Prenatal Test for Monogenic Disease, a test for families at-risk for rare diseases.

Progenity also manages a laboratory in Lubbock, Texas that markets a range of anatomic and molecular pathology tests and specialized genetic tests. Professional services are provided by Mattison Pathology (dba Avero Diagnostics) under a long-term contract.

In filings with the U.S. Securities and Exchange Commission, Progenity said it will use the majority of the IPO proceeds to support its operations and fund development of new molecular tests.

Progenity also owes about $33 million to Cigna, Aetna and United HealthCare for recently reached agreements to settle claims related to past billing and coding practices that Progenity has discontinued. Specifically, in December 2018, Progenity agreed to pay Cigna $12 million on behalf of Avero, of which $2.5 million remains outstanding. In September 2019, Progenity agreed to pay United $30 million, of which $23 million is still owed. And in November 2019, the company entered into a $15 million settlement with Aetna, of which $7.5 million remains.

Furthermore, in March, Progenity agreed to pay $49 million over a five-year period to resolve criminal and civil charges filed by the U.S. Department of Justice and the State of New York over discontinued billing practices for its NIPT tests, as well as alleged kickbacks or inducements made to physicians and patients.

Progenity recorded a net loss of $17.2 million for the three months ended March 31, 2020, versus a net loss of $27.7 million for the same period a year earlier; revenue declined to $16.8 million from $47.5 million. During the three months ended March 31, 2020 and 2019, Progenity's revenue was reduced by $13.4 million and $0.5 million, respectively, for accruals for reimbursement claims and settlements with payers, DOJ and State AGs.

Since being formed in 2012 through March 31, 2020, Progenity has accumulated losses totaling $365.6 million.

Following the IPO, Progenity's largest stockholder is Athyrium Capital Management (New York City), which has a 42.7% stake. In addition, Progenity's Chairman and CEO, Harry Stylli, PhD, owns 31.4%.

Progenity Financial Summary ($ 000)

	First-Quarter 2020	*Full-Year 2019*	*Full-Year 2018*
Revenue	$16,828	$143,985	$127,974
Loss from operations	-52,526	-140,119	-114,239
Net loss	-17,152	-148,037	-129,106
Test volume	79,000	329,000	269,000

Source: Progenity IPO filing

Spotlight Interview with DV & Associates CEO Diana Voorhees

Laboratory Economics recently spoke with Diana Voorhees, CEO of DV & Associates, Inc. (Salt Lake City), a coding and reimbursement consulting firm focused on pathology and laboratory medicine, about coding and billing issues associated with Covid-19 testing.


Diana Voorhees

How many codes are there now for PCR-based Covid testing? What are the primary ones?
There's 135 for PCR, 22 for serology antibody testing and only one for antigen testing, which is done by Quidel (see page 10). They have their own platform for infectious agent testing called Sofia, which a lot of physician offices already have.

What are the codes and average payment for these tests?
For antigen testing, the CPT code is 87426, which is an immunoassay. We don't know reimbursement for that yet. The very first code for PCR testing came from Medicare so people could start billing HCPCS codes—U001 for the CDC test, which pays $36, and U002 for non-CDC tests, which pays $51. These codes were announced before the AMA came out with its Covid PRC CPT code 87635, which pays $51. The U codes are still being used, especially for point-of-care testing.

What about high-throughput testing?
There are a lot of instruments that do high-volume PCR testing—Roche, Abbott, Hologic, GeneXpert. If you can do a lot of tests in a day, you get paid more. To be considered as high-throughput, more than 200 tests per day must be analyzed. There are two codes for high-throughput: U0003, for tests that would otherwise be coded 87635, and U0004, which is for non-CDC high-throughput tests. These are high-complexity tests that are reimbursed at $100 through Medicare.

Are there different codes for point-of-care tests?
No. Abbott ID Now is a point-of-care PCR test, which would be reported with 87635 or reported with U0002. Right now, both codes are being used. They are both being accepted although some moderately complex laboratories or point-of-care sites are not getting reimbursed. It's best to add the QW modifier to get make sure you get appropriate payment.

Are labs having problems getting paid for Covid-19 testing?
I am hearing that the high-throughput codes are not being reimbursed fully. Even though the CARES [Coronavirus Aid, Relief and Economic Security] Act says there is no cost sharing, some payers apparently are not paying the full amount and trying to apply cost sharing. The way to get around that is to add the CS modifier, which means there is no cost sharing. Many labs don't know about it, but if they get denied, they can rebill.

What about coding and payment for antibody testing?
There are two codes for antibody testing. Antibody testing does not have a high confidence level right now. There are so many different tests with questionable validity although CDC has tightened up on it. CPT 86328 is for a single step method—such as point of care done in physician offices—that pays $45.23. The second one, 86769, is for routine high-complexity tests with multiple steps, and that is reimbursed at $42.13. You would think the reimbursement would be reversed.

What are home test kits being paid?
The LabCorp Pixel test is the only one to allow a patient to swab their nose at home. They have to have a physician order, reserve the test with LabCorp and pay $115 up front. There have been some concerns about the quality of the specimen that someone provides at home—concerns about possible contamination by the patient. Four states are not allowing the testing—New York, New Jersey, Rhode Island and Maryland.

Do you expect to see more Covid-19 testing codes to be released?
Yes. There are new proprietary laboratory analyses (PLA) codes that were announced for July 1. The first one, 0202U, is for BioFire's respiratory panel, including Covid, and is effective May 20. Quiagen's test for infectious agents (bacterial or viral), including SARS-CoV-2, was assigned code U223U, and is effective July 1. We don't know the reimbursement on these yet. Payment is determined by each payer. But just having the code doesn't mean you'll get paid.

U224U is for a test developed by Mt. Sinai Laboratory. It's a qualitative antibody test on blood or serum for Covid-19. If the test is positive, the patient goes on to do a titer. This could be used for a recovered person who might have viable plasma antibodies for therapeutic purposes.

There is also a new ICD-10 diagnosis code put out by the World Health Organization—U07.1 (effective April 1, 2020). There also are codes for people who are positive but asymptomatic.

What other billing and coding issues are labs dealing with right now?
The CARES Act included some provisions that affect laboratories and pathologists. It impacted PAMA by putting a hold on the 15% Medicare reduction scheduled to take effect next year. It also eliminated the 2% sequester, although I've heard that some labs are still getting hit by the 2% sequester. The CARES Act addresses periods of time impacted by the pandemic.

The CARES Act also mandates coverage for Covid-19 testing and says there will be no cost-sharing for Covid testing for all payers.

The act also allows pathologists who work from home, in a different state, to report the primary address of the hospital where they work.

One thing that concerns me is whether labs are paying attention to auditing and monitoring that they should be doing. Labs can't back off compliance just because of the pandemic. I am concerned about HIPAA privacy, policies and procedures for quality assurance, personnel issues, exposure and safety issues. A lot of things have been put on hold. I think there will be whistleblower cases and lawsuits down the road.

Pathology Groups And Labs Should Expect 100% PPP Loan Forgiveness

New modifications to the Paycheck Protection Program (PPP) have made it much easier for independent pathology groups and clinical labs that obtained PPP loans to obtain full loan forgiveness, according to Robert Tessier, Senior Reimbursement Consultant at HBP Services (Woodbridge, CT), which provides consulting services to pathology practices.


Robert Tessier

The PPP was created by the CARES Act to provide forgivable loans to eligible small businesses to keep American workers on the payroll during the Covid-19 pandemic. The legislation authorized the U.S. Treasury to use the Small Business Administration's lending program to fund loans of up to $10 million per borrower to cover payroll, mortgage interest, rent/lease and utilities (electricity, phone, internet access, et al.). PPP loans were made available to small businesses that were in operation as of February 15 with 500 or fewer employees, including sole proprietorships and independent contractors.

Tessier says that all of his pathology group clients obtained PPP loans in April or May for amounts ranging from $100,000 for a three-pathologist group to $1.8 million for a nine-pathologist group with a large histology lab.

Under the original PPP rules, small businesses could deduct eight weeks' worth of employee salaries and other expenses from their loan amounts. This meant that most pathology groups and labs that got PPP loans would have received about 75% loan forgiveness and then had to pay back the remaining 25% within two years with 1% interest.

However, on June 3, the U.S. Congress passed the Paycheck Protection Program Flexibility Act of 2020 (PPPFA), which modified the original PPP loan program, making it easier for borrowers to get 100% loan forgiveness.

Key provisions of the PPPFA include:

- A longer period for borrowers to use the funds to pay for payroll and eligible business expenses (8 weeks → 24 weeks).
- At least 60% (down from 75%) of the loan proceeds must be used for payroll costs, while up to 40% (up from 25%) can be used for nonpayroll costs.
- Repayment of any non-forgivable loan amount is due within 5 years (up from 2 years).

For example, Tessier says that a hypothetical hospital-based pathology group structured as a C-Corporation with four pathologist owners and one full-time administrative employee might have gotten a $150,000 PPP loan in early May. This group would be able to deduct the maximum allowed for owner-employee compensation of $20,833 per pathologist plus $46,154 for its non-owner FTE (4 x $20,833 plus $46,154=$129,486). That would leave this group with $20,514 of PPP loan amount that could be offset by eligible nonpayroll expenses for rent/lease and utility costs incurred over 24 weeks after their loan was received as well as health benefits and retirement contributions, depending on how the practice is structured. Tessier anticipates that all groups will obtain full PPP loan forgiveness.

In addition, Tessier says that all of his clients received funding from the HHS Provider Relief Fund (PRF), which was authorized under the CARES Act to assist the healthcare industry in combating the Covid-19 pandemic. PRF payments were based upon 2% of each provider's 2019 or 2018 income (depending on which tax return was submitted) after being reduced by a previous automatic Medicare grant. The automatic grant was 6.2% of each provider's Medicare FFS payments in 2019. Tessier says that most of his clients received PRF and automatic grant payments of between $75,000 and $125,000, with one large group receiving over $250,000. He notes that PRF payments are not loans and will not need to be repaid.

Tessier says that his pathology group clients saw their referred case volume decline by roughly 80% in late March through May, while inpatient case volumes declined by about 50%. Pathology volumes improved in June and should be back up to 90% of pre-pandemic levels in July, according to Tessier.

He notes that the combination of PPP loans and PRF payments helped independent pathology groups and clinical labs only partially bridge the huge temporary drop in volume they suffered as a result of the pandemic lockdown.

Labs that Got the Biggest PPP Forgivable Loan Amounts

On July 6, the U.S. Treasury Department released the names of more than 650,000 companies that received PPP loans. More than 1,000 lab and pathology companies received PPP loans, including six companies that got the maximum loan range amount of $5 million to $10 million.

Labs That Received Biggest PPP Forgivable Loans (between $5 million and $10 million)

Laboratory Name	*City*	*State*	*Jobs Retained*
Accu Reference Medical Lab	Linden	NJ	499
Amerathon	Cincinnati	OH	500
Incyte Pathology	Spokane Valley	WA	373
Medical Diagnostic Laboratories	Trenton	NJ	NA
National Medical Services (NMS Labs)	Horsham	PA	363
Propath Holdings	Dallas	TX	471

Source: https://www.sba.gov/funding-programs/loans/coronavirus-relief-options/paycheck-protection-program#section-header-11

Top 25 Lab and Pathology Companies Receiving PRF Payments

Not surprisingly, Quest Diagnostics ($65 million) and LabCorp ($56 million) top the list in terms of highest PRF payments received by lab and pathology companies. Exact Sciences, including Genomic Health, received $23.5 million, while Sonic Healthcare, including Aurora Diagnostics, received $12.4 million. In total, the top 25 lab and pathology companies received $222.6 million in PRF payments.

Top 25 Lab and Pathology Companies Receiving PRF Payments

Laboratory Name	*City*	*State*	*PRF Payment*
Quest Diagnostics	Secaucus	NJ	$65,000,000
LabCorp	Burlington	NC	$56,000,000
Exact Sciences/Genomic Health	Madison	WI	$23,474,349
Sonic Healthcare/Aurora Diagnostics	Austin	TX	$12,432,412
Myriad Genetics	Salt Lake City	UT	$7,953,513
Inform Diagnostics	Irving	TX	$6,843,500
BioReference Labs/GeneDx	Elmwood Park	NJ	$5,771,802
CareDx	Brisbane	CA	$4,813,247
NeoGenomics/Genoptix	Fort Myers	FL	$4,014,136
Sonora Quest Laboratories	Tucson	AZ	$3,829,381
Invitae Corp.	Irvine	CA	$3,793,677
PathGroup/Associated Pathologists	Brentwood	TN	$3,652,636
Aegis Sciences Corp.	Nashville	TN	$3,214,105
Caris MPI	Phoenix	AZ	$2,639,444
Millennium Health	San Diego	CA	$2,598,943
American Health Associates/Amerathon	Miramar	FL	$2,494,161
ACM Medical Laboratory	Rochester	NY	$1,797,346
Bakotic Pathology Associates	Alpharetta	GA	$1,698,423
Northwell Health Laboratories	Lake Success	NY	$1,611,587
Tricore Reference Laboratories	Albuquerque	NM	$1,553,073
Interpath Laboratory	Pendleton	OR	$1,496,038
Enzo Clinical Labs	Farmingdale	NY	$1,495,515
Empire City Laboratories	Brooklyn	NY	$1,485,573
Guardant Health	Redwood City	CA	$1,469,350
Gamma Healthcare	Poplar Bluff	MO	$1,467,354
Total, top 25 labs			$222,599,565

Source: https://data.cdc.gov/Administrative/HHS-Provider-Relief-Fund/kh8y-3es6

UHC Hits Texas Pathologists With ~50% Rate Cuts (*cont'd from p. 1*)

The letter goes on to state that anyone who does not agree to the new contract must notify UHC within 30 days of receipt of the notice. The exact amount of the cut depends on the provider's existing contract, notes Lambrix.

Lambrix says that UHC's new pathology rates in Texas are roughly equivalent to 120% to 150% of Medicare rates for 2019. This compares to legacy contracts that had paid at roughly 200% to 300% of current Medicare rates.

UHC's letters notifying Texas pathologists of the change were received as early as February by some groups and appear to have been received as late as this month by other groups, according to Lale White, Chairman and CEO at XIFIN Inc. (San Diego, CA). She notes that many pathologists have been in negotiation since receiving notices and a number are already being paid at new contract rates.

White notes that most pathology groups saw a 50+% decline in their volume during the depths of the quarantine and have not been able to make it up with added Covid-19 testing unlike many routine clinical labs. "Essentially payers have already received a windfall from pathology providers as a result of volume declines and it seems egregious for them to now hit pathologists with such extreme reimbursement cuts."

Meanwhile, Lambrix says that so far she is unaware of any pathology groups that have received similar notices from UHC in other states. However, she says that she would not be surprised if pathologists in other states start getting UHC notices—similar to how Anthem BCBS rolled out its rate cuts across the country in 2018-2019 (see *LE*, July 2019).

Lambrix believes that many pathology groups in Texas may have disregarded UHC's letter and will only realize the extent of the rate cuts when lower reimbursement checks start hitting their bank statements. She urges pathology groups to review all their insurance contracts to ensure they include language that requires that any material change, especially to reimbursement rates, be signed off on by both parties. At a bare minimum, she says that participating providers should be given 90 days advance notice before the effective date of any material contract amendment.

Finally, the College of American Pathologists (CAP) is urging UHC to suspend implementation of the new pathology fee schedule in Texas. CAP has requested a meeting with UHC's network contracting executives to discuss the rationale for the rate cuts given the financial strain that pathologists now face as a result of the Covid-19 crisis.

Agendia To Pay $8 Million To Settle Alleged 14-Day Rule Violations

Agendia Inc. (Irvine, CA) has agreed to an $8.25 million settlement with the federal government to resolve allegations of a nationwide scheme to bill Medicare for the company's MammaPrint gene expression profiling test for breast cancer, the Justice Department announced June 25.

Agendia was accused of conspiring with hospitals across the country to artificially delay ordering MammaPrint tests to get around Medicare's 14-day rule. That rule is meant to prevent labs from billing Medicare separately for tests if a doctor ordered them within 14 days of when a patient was released from a hospital. If a test is performed after that 14-day period, the rule allows labs to bill Medicare directly for the test. MammaPrint (CPT 81521) currently has a Medicare CLFS rate of $3,873.

The Justice Department said the accusations against Agendia first became public in a lawsuit filed by a former employee of Lourdes Hospital, now called Mercy Health. In a separate settlement in 2017, Mercy Health/Lourdes Hospital paid the U.S. government $211,039 to settle allegations that the hospital worked with Agendia as part of the scheme.

Quidel Gets EUA For First Covid-19 Antigen Test

Quidel Corp. (San Diego, CA) has received Emergency Use Authorization (EUA) from the FDA to run its new SARS antigen test on its Sofia 1 (EUA granted June 9) and Sofia 2 (EUA granted May 8) desktop immunoassay analyzers. The rapid point-of-care test detects an active Covid-19 infection with results in 15 minutes from nasal or nasopharyngeal specimens.

Quidel reports that the test is 100% specific and 80% sensitive. In 143 nasopharyngeal samples, there were zero false positives and 12 false negatives (see table below). Given the higher chance of false negatives (20%), FDA said that negative results from the antigen test may need to be confirmed with a PCR test prior to making treatment decisions.

At the end of June, Quidel had 45,000 Sofia analyzers installed in hospitals and physician offices worldwide, 90% of which are in the U.S.

The cost to labs for each test cartridge is roughly $20. Cardinal Health, Fisher Healthcare, Henry Schein and McKesson are acting as distributors.

Quidel says that it has ramped up manufacturing from 200,000 antigen tests per week in mid-May to currently more than a million per week. "We expect that we will ship every cartridge that we can manufacture for the foreseeable future," according to Douglas Bryant, President and CEO of Quidel.

The code for the test is CPT 87426. Medicare has not yet set a reimbursement rate.

Becton Dickinson Gets EUA for Rapid Antigen Test

On July 6, Becton Dickinson (BD-Franklin, NJ) received EUA from FDA for its new rapid antigen test for Covid-19. The test is performed using nasal swab specimens on the BD Veritor Plus System, which is currently in use at more than 25,000 hospitals, physician offices and retail pharmacies in the United States. In clinical studies, the test correctly identified 84% of samples positive for Covid-19 while delivering zero false positives, according to BD. The company has begun shipping the new test and expects to produce up to 10 million tests from July through September. Manufacturing capacity is expected to reach two million tests per week by the end of September.

OraSure Developing At-Home Covid-19 Test

OraSure Technologies (Bethlehem, PA) is developing an oral fluid antigen test. The 20-minute test will allow for in-home self-testing by lay users as well as by medical professionals. No instrumentation or trained personnel will be needed to administer the test or to read the results. OraSure is hoping to receive EUA and begin marketing the test in September.

Testing Accuracy Comparison for Point-of-Care Covid-19 Diagnostic Tests

			Nasal Swab		*Nasopharyngeal Swab*	
Manufacturer	*System*	*Detection Method*	*Sensitivity*	*Specificity*	*Sensitivity*	*Specificity*
Becton Dickinson	Veritor Plus	antigen	84% (26/31)	100% (195/195)	NA	NA
Quidel	Sofia 1&2	antigen	80% (4/5)	100% (43/43)	80% (47/59)	100% (84/84)
Abbott	ID Now	iosthermal	NA	NA	100% (30/30)	100% (30/30)
Cepheid	GeneXpert	PCR	NA	NA	100% (30/30)	100% (35/35)

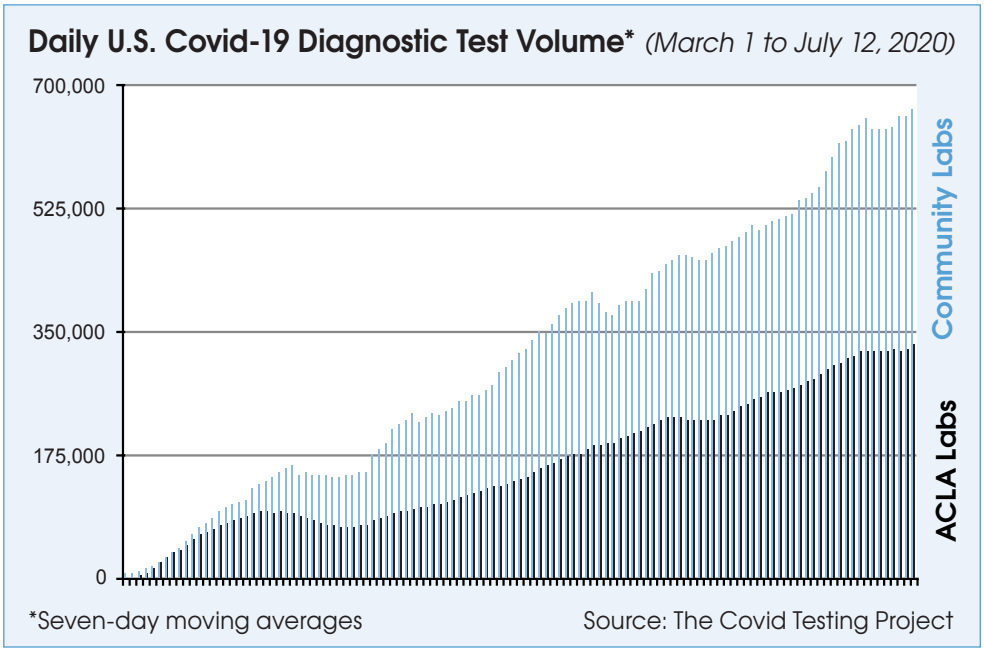
Source: Nephron Research and test package inserts

Covid-19 Test Volumes Continue To Surge

U.S. Covid-19 diagnostic testing volumes increased by nearly 50% over the past month, although supply shortages are delaying turnaround times and limiting many labs from reaching their full capacity. Average overall U.S. daily volume for Covid-19 diagnostic testing reached 667,000 in the week ended July 12, up from 464,000 a month earlier, according to the Covid Tracking Project, which gathers testing data from each state.

ACLA-member labs are consistently performing about 50% of Covid-19 tests, while hospitals and independent labs perform the other half.

Meanwhile, most labs continue to report ample supplies and capacity to perform Covid-19 antibody testing, but significant demand has not materialized.



Quest Diagnostics is currently performing about 114,000 Covid-19 PCR tests per day (near full capacity). Quest is also performing an average of 14,000 antibody tests per day (versus capacity of 200,000/day). Quest has reported that its core testing volumes (excluding Covid-19 testing) decreased by approximately 34% in the second quarter (ended June 30). Including Covid-19 PCR and antibody testing, Quest says that its second-quarter overall test volumes were down by approximately 18%.

LabCorp is currently performing about 111,000 Covid-19 PCR tests per day (versus capacity of 130,000/day) and 13,000 antibody tests per day (versus capacity of 300,000/day).

BioReference Labs reports that it's performing more than 50,000 Covid-19 PCR tests per day. BioReference recently announced a contract to provide Covid-19 PCR and antibody testing to the National Basketball Association's (NBA) players and referees, as well as team and league staff participating in the NBA's season restart in Orlando.

Lab Stocks Up 35% Year To Date

Twenty one lab stocks have jumped by an unweighted average of 35% year to date through July 10. In comparison, the S&P 500 Index is down 1% so far this year. The top-performing lab stocks thus far in 2020 are Aspira Women's Health (formerly named Vermillion), up 337%; Opko Health, up 173%; and Biocept, up 141%. Shares of LabCorp are up 2%, while Quest Diagnostics is up 9%.

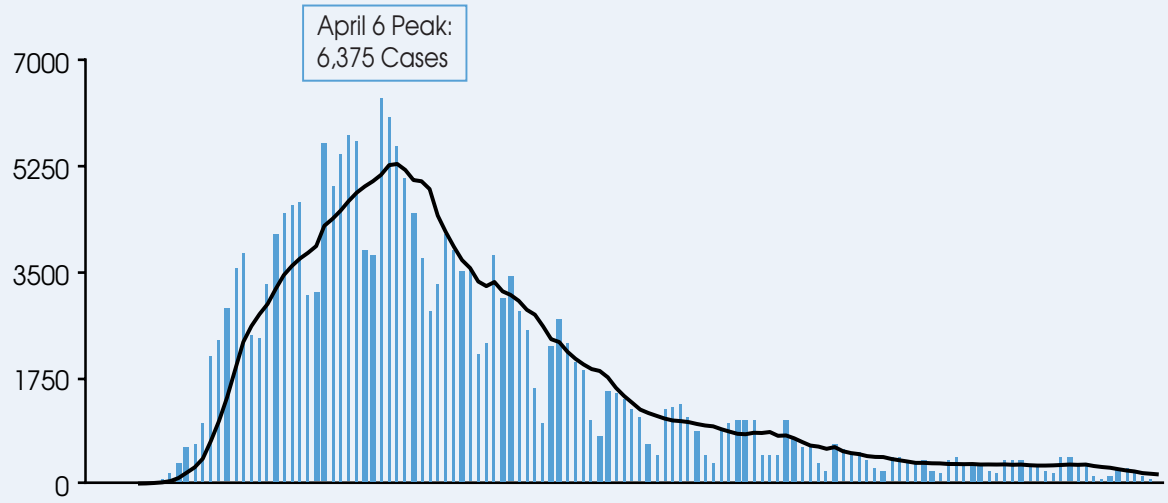
Company (ticker)	Stock Price 7/10/20	Stock Price 12/31/19	2020 Price Change	Enterprise Value ($ mill)	Enterp Value/ Revenue	Enterp Value/ EBITDA
LabCorp (LH)	$172.68	$169.17	2%	$23,750	2.1	16.9
Quest Diagnostics (DGX)	116.82	106.79	9%	20,020	2.6	13.5
Sonic Healthcare (SHL.AX)*	30.51	28.75	6%	18,290	2.8	14.1
Exact Sciences (EXAS)	92.08	92.48	0%	14,340	13.5	NA
Guardant Health (GH)	85.21	78.14	9%	8,180	33.3	NA
Invitae (NVTA)	33.47	16.13	108%	4,310	17.9	NA
NeoGenomics (NEO)	35.85	29.25	23%	4,030	9.6	111.8
Natera (NTRA)	46.92	33.69	39%	2,990	11.0	NA
Opko Health (OPK)	4.02	1.47	173%	2,970	3.3	NA
CareDx (CDNA)	33.93	21.57	57%	1,680	12.1	NA
Veracyte (VCYT)	29.00	27.92	4%	1,340	11.0	NA
Myriad Genetics (MYGN)	11.47	27.23	-58%	965	1.3	NA
Castle Biosciences (CSTL)	41.75	34.37	21%	718	11.9	60.1
Progenity (PROG)	9.53	15.00	-36%	479	4.2	NA
Aspira Women's Health (VRML)	3.54	0.81	337%	360	72.7	NA
DermTech Inc. (DMTK)	12.12	12.40	-2%	156	31.8	NA
Enzo Biochem (ENZ)	2.86	2.63	9%	100	1.3	NA
Exagen (XGN)	10.62	25.40	-58%	92	2.3	NA
Biocept (BIOC)	0.70	0.29	141%	73	12.3	NA
Interpace Biosciences (IDXG)	5.17	5.00	3%	58	2.1	NA
Psychemedics (PMD)	5.29	9.15	-42%	30	0.8	6.5
Unweighted Averages			35%	$104,931	12.4	37.1

*Sonic Healthcare's figures are in Australian dollars

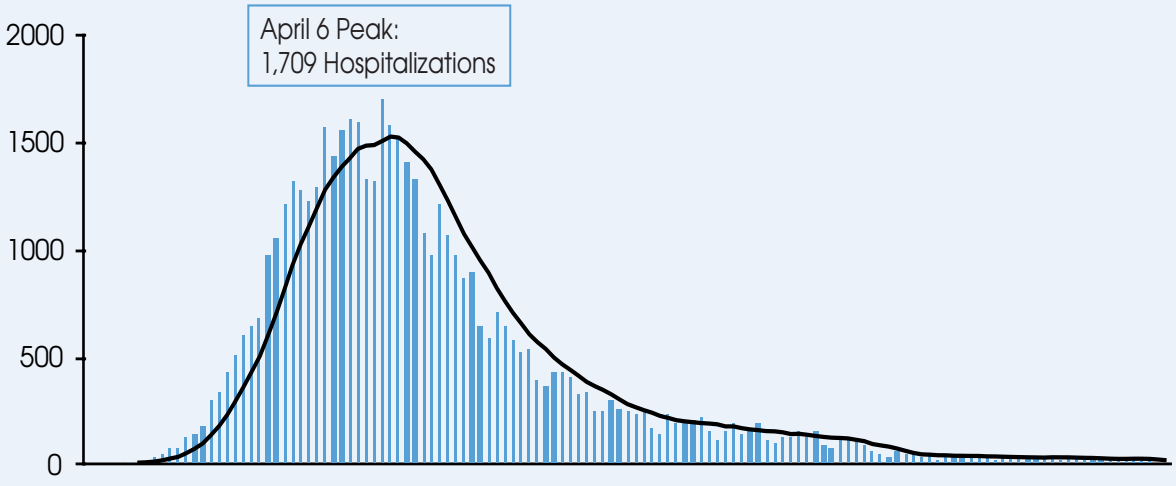
Source: *Laboratory Economics* from company reports and Capital IQ

Jondavid Klipp, Editor and Publisher Jennifer Kaufman, Associate Editor Kimberly Scott, Associate Editor

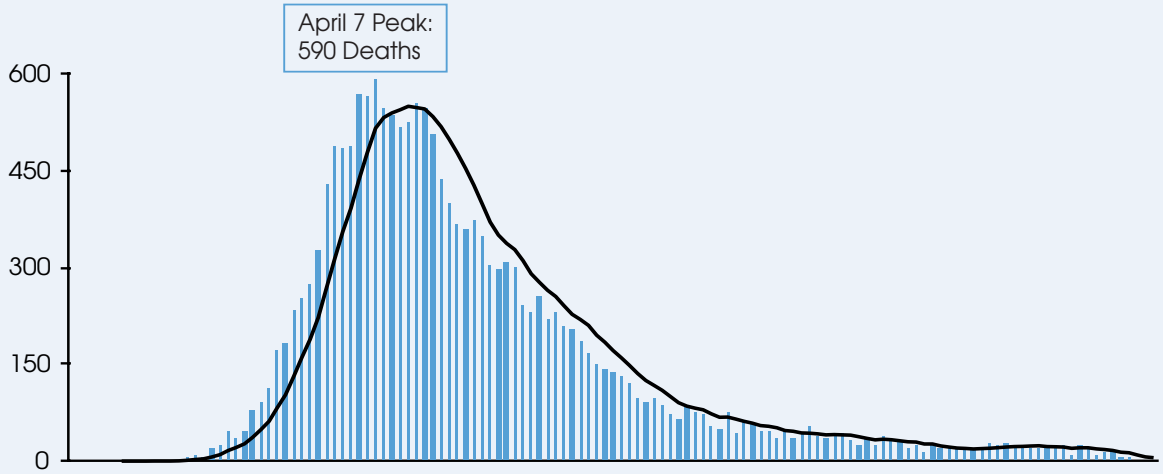
New York City Daily New Cases of Covid-19 with 7-Day Moving Avg. *(March 1 through July 11, 2020)*



NYC Daily New Hospitalizations from Covid-19 with 7-Day Moving Avg. *(March 1 through July 11, 2020)*

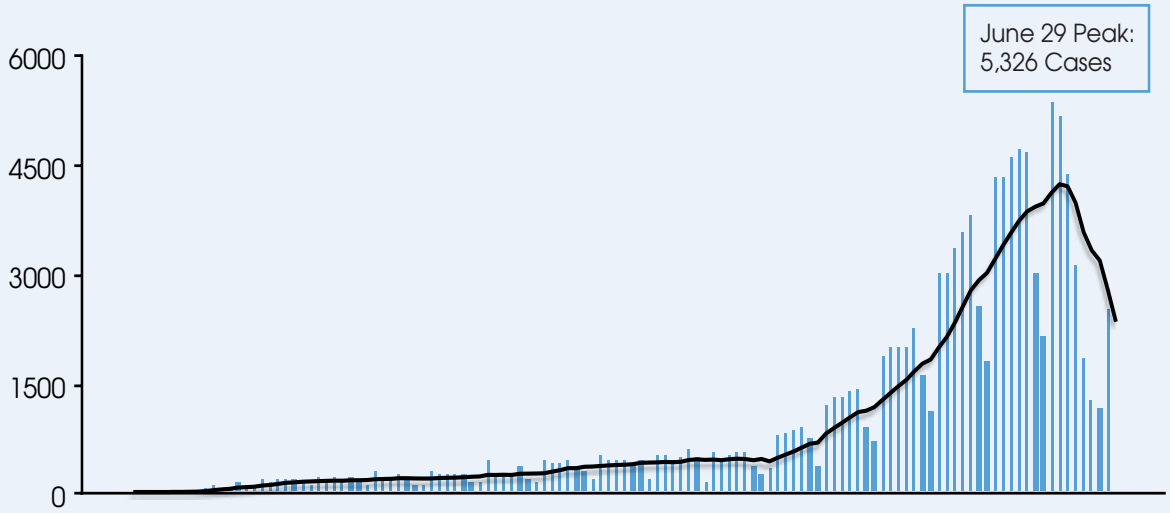


New York City Daily Deaths from Covid-19 with 7-Day Moving Avg. *(March 1 through July 11, 2020)*

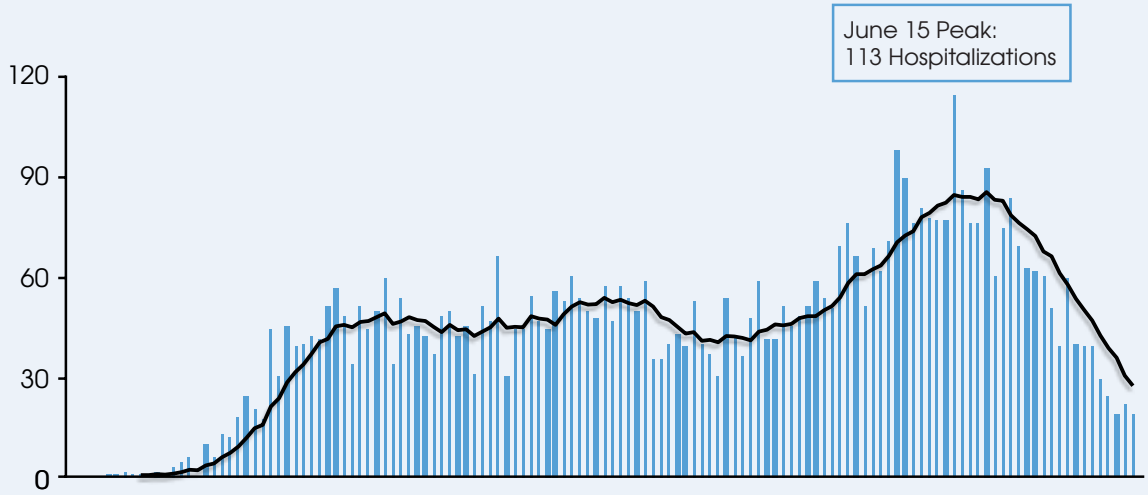


Source: NYC Department of Health and Mental Hygiene

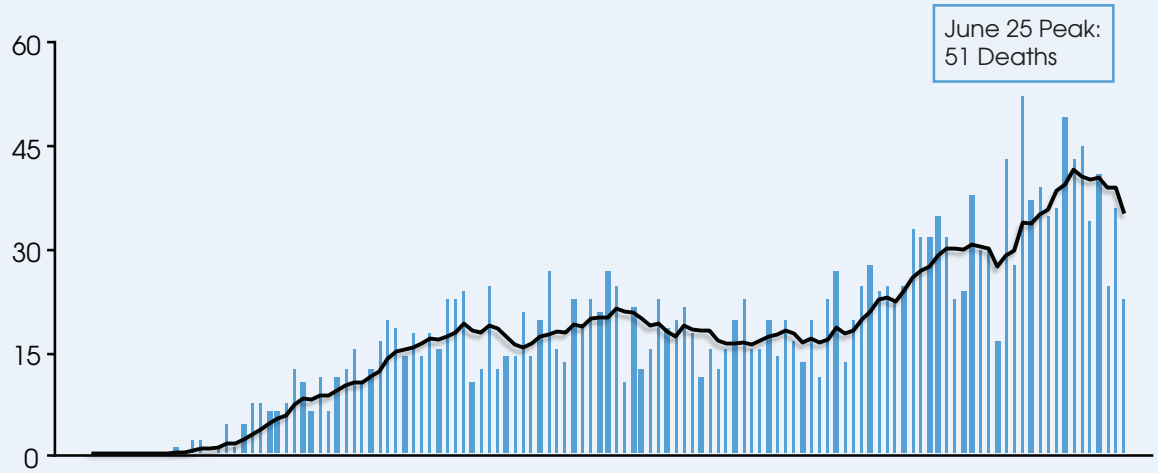
Arizona Daily New Cases of Covid-19 with 7-Day Moving Avg. *(March 1 through July 7, 2020)*



Arizona Daily New Hospitalizations from Covid-19 with 7-Day Moving Avg. *(March 1 through July 7, 2020)*

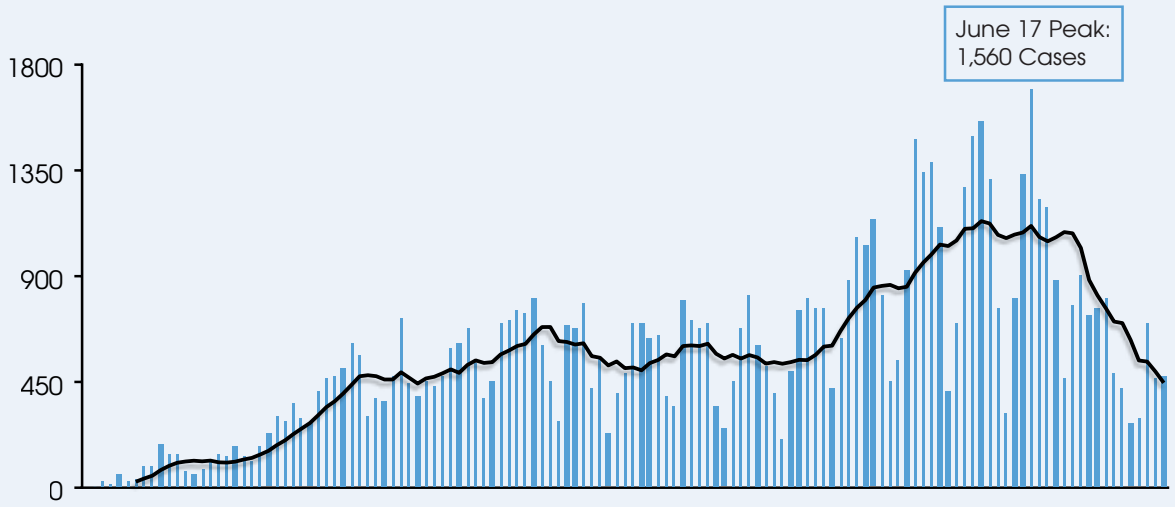


Arizona Daily Deaths from Covid-19 with 7-Day Moving Avg. *(March 1 through July 7, 2020)*

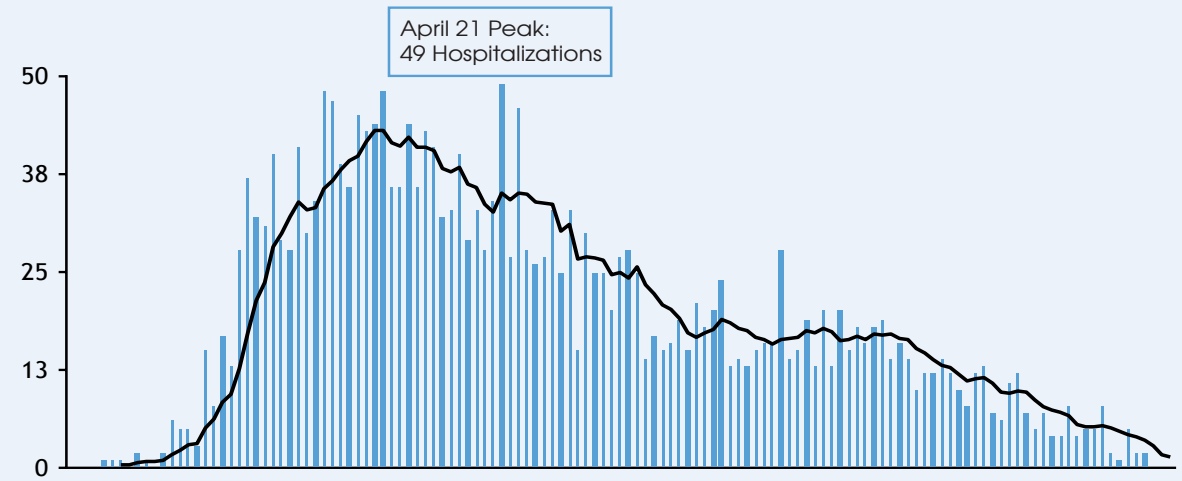


Source: Arizona Department of Health Services

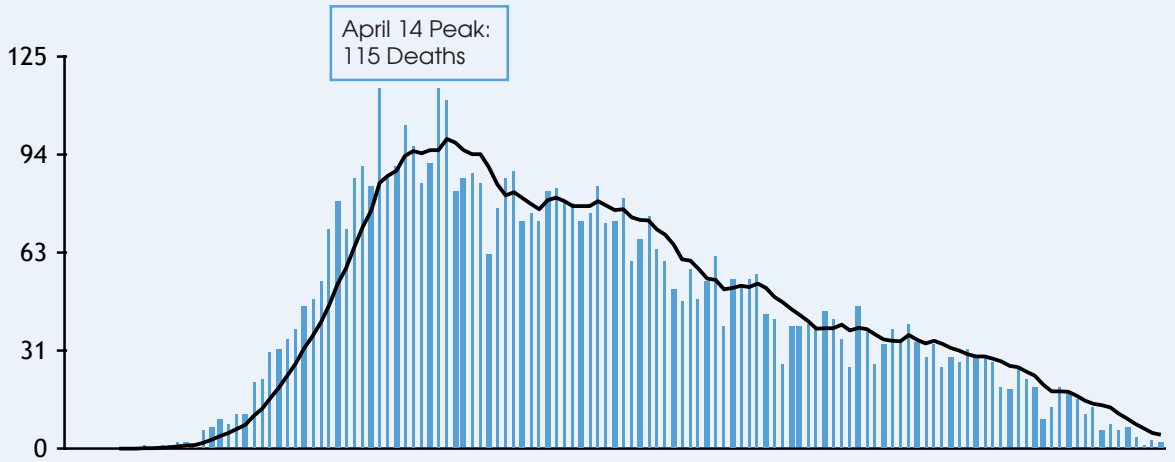
Sweden's Daily New Cases of Covid-19 with 7-Day Moving Avg. *(March 1 through July 9, 2020)*



Sweden's Daily ICU Admissions for Covid-19 with 7-Day Moving Avg. *(March 1 through July 9, 2020)*



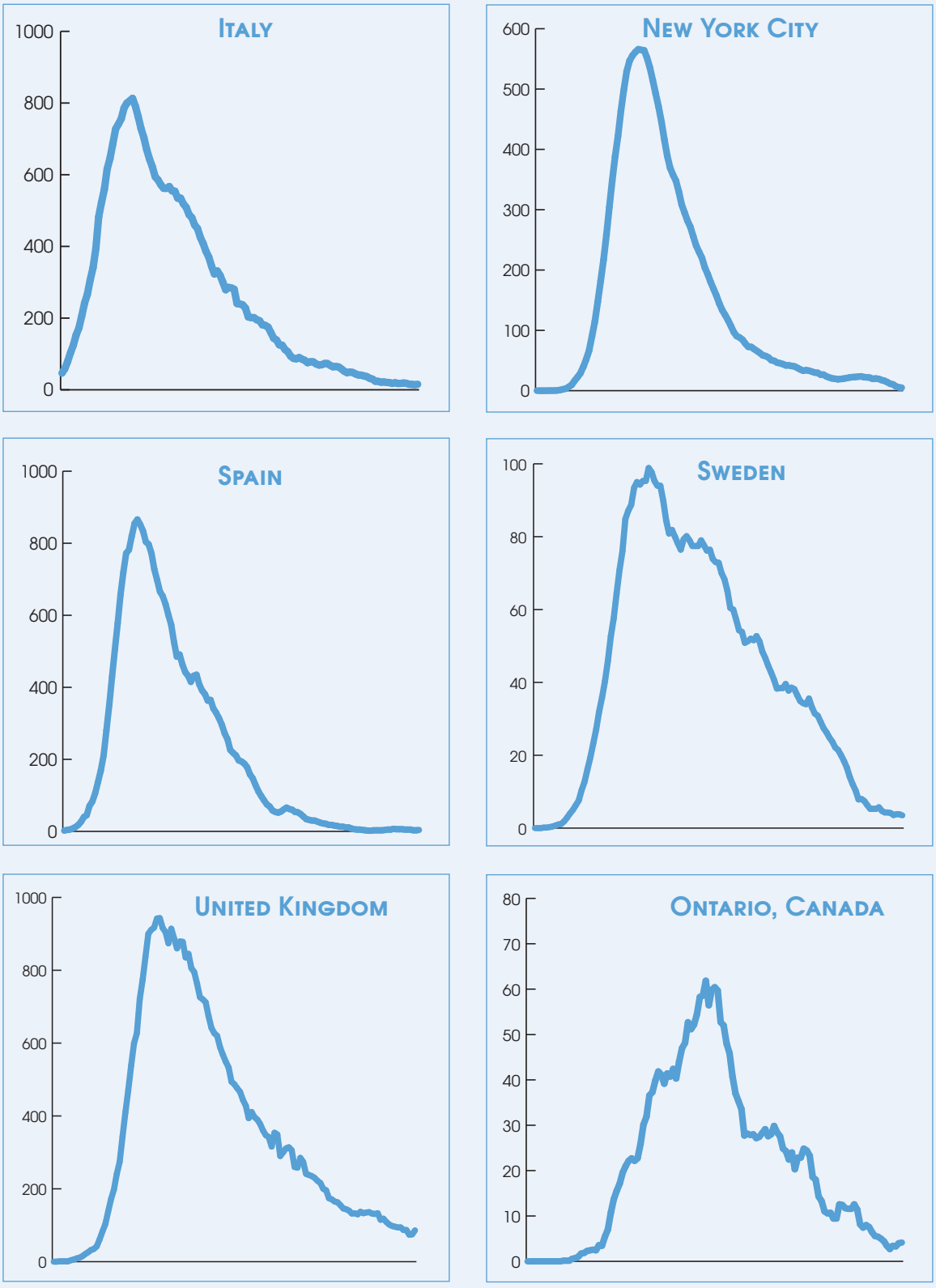
Sweden's Daily Deaths from Covid-19 with 7-Day Moving Avg. *(March 1 through July 9, 2020)*



Source: Folkhälsomyndigheten (https://experience.arcgis.com/experience/09f821667ce64bf7be6f9f87457ed9aa)

Daily Covid-19 Deaths At Six Outbreak Locations

(Graphs show seven-day moving average of daily Covid-19 deaths from March 7 through July 11, 2020)



Source: Worldometers and each location's Public Health Dept.