

# LABORATORY



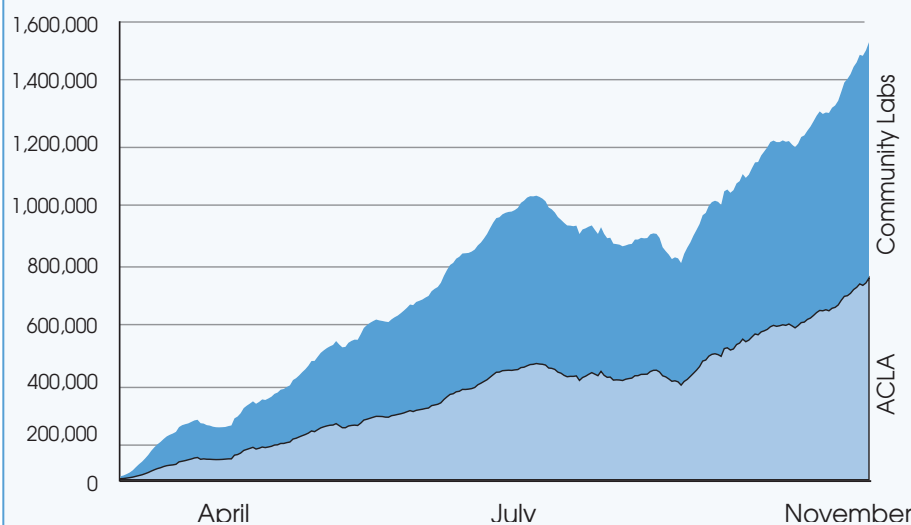
# ECONOMICS

*Competitive Market Analysis For Laboratory Management Decision Makers*

## Covid-19 PCR Test Volumes Hit 1.5 Million Daily; Supply Shortages Impacting Non-Covid-19 Testing

The average daily volume of Covid-19 PCR testing performed in the United States has reached 1.5 million tests for the seven days ended November 14, according to the Covid Tracking Project. ACLA member labs' share of Covid-19 PCR testing is now averaging 30% and hospitals and independent labs are doing 70%.

Daily U.S. Covid-19 PCR Test Volume\* (March 16 to November 14, 2020)



\*Seven-day moving average

Source: The Covid Testing Project and ACLA

The extraordinary volume of Covid-19 testing has affected the production of supplies required to test for all kinds of other infectious diseases and caused a ripple effect of shortages for non-Covid-19 microbiology tests, according to an ongoing survey being conducted by the American Society for Microbiology. *Details on page 5.*

## Exact Sciences To Buy Thrive For \$2 Billion

Exact Sciences has agreed to acquire Thrive Earlier Detection Corp. (Cambridge, MA) for as much as \$2.15 billion, including \$1.7 billion payable at closing, comprised of 65% in Exact common stock and 35% in cash. An additional \$450 million is payable based on performance milestones related to FDA clearance, Medicare coverage, and pricing for Thrive's CancerSeek, a blood-based, multi-cancer screening test. *Continued on page 2.*

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**Exact Sciences To Buy Thrive For \$2 Billion** (*cont'd from page 1*)

Johns Hopkins spun out Thrive in early 2019 with the aim of commercializing CancerSEEK. The company raised \$110 million from private equity investors in May 2019 and another \$257 million in July 2020. Investors include Third Rock Ventures, Casdin Capital, Section 32, BlueCross BlueShield Venture Partners and Exact Sciences.

Exact's purchase was motivated by the successful completion by Thrive of a prospective study of its CancerSEEK test. The study was conducted by Johns Hopkins University and Geisinger Health System, and enrolled 9,911 women between the ages of 65 and 75 with no prior history of cancer. Blood specimens were taken from the women between September 2017 and May 2019 at 18 Geisinger Health clinic sites. The purpose was to identify multiple cancer types in asymptomatic individuals using an early version of CancerSEEK.

The CancerSEEK test panel included tests for mutations in 16 genes known to drive the growth of various cancers (e.g., BRAF, EGFR, KRAS, TP53, et al.) plus nine commonly used protein biomarkers for cancer (CA15-3, CA19-9, CA125, CEA, et al.). The panel components were selected by Bert Vogelstein, MD, Ken Kinzler, PhD and Nick Papadopoulos, PhD at Johns Hopkins University. Study results were published in peer-reviewed *Science* (July 3, 2020).

The study found that the CancerSEEK test detected 10 types of cancer, including ovarian, pancreatic and liver, in 26 women that would not have otherwise been found. Fifteen of these cases underwent PET-CT imaging and nine were surgically excised. Standard-of-care screening (mammogram, breast imaging, Pap tests, colonoscopies, et al.) detected 24 additional cancers that were missed by CancerSEEK. Another 46 cancer cases were identified by other means, for a total of 96 cancers diagnosed. Overall, 101 participants (1%) underwent PET-CT imaging due to false-positive CancerSEEK tests and 22 women (0.22%) underwent a futile invasive diagnostic procedure. The sensitivity, specificity, and positive predictive value of CancerSEEK when combined with imaging were 27.1%, 99.6%, and 40.6%, respectively.

Thrive has since had extensive discussions with FDA concerning the study design for a new 80,000-patient pivotal study for an improved CancerSEEK test. Analysts have suggested that multi-cancer blood tests like CancerSEEK might ultimately be paid at \$500 to \$1,000 per test.

Exact hopes to complete the acquisition of Thrive early next year.

In addition to potential FDA clearance, Exact is considering bringing CancerSEEK to market as a laboratory-developed test. Either way, Exact believes that its payer relationships, direct-to-consumer marketing experience and 1,000+ sales and marketing staff will accelerate commercialization.

**Exact also Acquires Base Genomics**

Separately, Exact also announced that it acquired Base Genomics (Cambridge, England) on October 26 for \$410 million in cash. Base Genomics was spun out of the University of Oxford earlier this year to develop and commercialize a DNA methylation-based blood test for early-stage cancer detection.

**Exact Reports Third-Quarter Results**

Exact reported third-quarter 2020 revenue of \$408 million, up 87% from \$219 million in the same period a year ago. Third-quarter 2020 revenue included \$215 million from Cologuard, \$92 million from Genomic Health cancer testing and \$102 million from Covid-19 testing. Third-quarter 2020 net loss was \$220 million versus a net loss of \$41 million. Exact has now accumulated losses totaling \$1.5 billion since being formed in 1995.

## Spotlight Interview With Stamford Health's Robert Babkowski

Stamford, Connecticut, located just north of New York City, got hit hard by the coronavirus pandemic this past spring. For a review of how the initial outbreak unfolded and an update on where the region currently stands, *Laboratory Economics* spoke with Robert C. Babkowski, MD, Chair, Department of Pathology and Laboratory Medical Director at Stamford Health System.



### What was Stamford Health's experience with the initial outbreak?

Stamford is only a 38-minute train ride to Manhattan, so we have a large commuter population. I believe trains and subways were big vectors for the spread of coronavirus. When New York City became the epicenter in the early spring, Stamford, in the southern corner of Connecticut followed.

At the height of the outbreak in April, Stamford Hospital had 149 Covid inpatients and a Covid-19 PCR test positivity rate of 40%.

As of November 13, Stamford Hospital had 31 Covid inpatients and our positivity rate for testing is averaging about 6%. College-age young adults currently represent the greatest share of positives and hospitalized patients are those with pre-existing conditions.

### How did your hospital cope with the initial big wave of patients?

We were lucky in many respects in that we had the platforms in-house prior to the pandemic to perform rapid Covid-19 PCR testing immediately once tests became available.

Stamford Health moved into a brand new 305-bed hospital in late 2016. The old location was kept intact and largely vacant. This location was designated by FEMA (the Federal Emergency Management Agency) as an Alternative Care Site for Covid patients in March. In a matter of weeks, the U.S. Army Corps of Engineers transformed the old hospital into a backup Covid facility. Two teams of 85 U.S. Army Reserve personnel worked around the clock along with all the staff at Stamford Health. In retrospect "it was the worst of times but the best of times" in that all had focus and feeling of purpose.

Stamford Health had 11 Abbott ID Now POCT devices in place at various outpatient locations before the pandemic started, as we have been using them for rapid flu testing for years. We moved all of these analyzers to our main lab at Stamford Hospital in mid-March and began using them for Covid-19 PCR testing. We were designated a "hot zone" and got priority access to Abbott ID Now cartridges. Our initial March volumes averaged 150-200 tests per day in the ED alone.

We also had existing Hologic Panther and Cepheid GeneXpert and Biofire systems in place because we have a high complexity microbiology lab. Once the former two rolled out their Covid tests, we were able to expand our testing further. We are currently performing about 1,000 Covid-19 PCR tests per day across multiple platforms.

Staffing was also not a problem. Because we have a large outreach business, we were able to shift all our phlebotomists placed in closed physician offices to become Covid swabbers throughout the organization and deployed them to nursing homes and assisted living facilities for sampling as well.

### What are your turnaround times?

Symptomatic patients entering our emergency department get a Biofire respiratory panel, flu and rapid Covid-19 PCR test with 90-minute turnaround. Our current turnaround time for all other Covid testing is within 24-48 hours.

**How is the supply situation?**

The reagent, swab, and transport media supply situation at Stamford Health is excellent. With tremendous support from our materials management and C-suite leadership, we have stocked up to weather any upcoming surge. We've learned the value of not being dependent on a single platform and how to manage testing across various platforms on a real-time basis. On the labor side, we are recruiting more registrars/test schedulers and nasal swab-trained personnel.

**Are private insurers matching Medicare reimbursement rates for Covid-19 testing?**

Connecticut state law requires private insurers to pay the same, or higher, rates as Medicare.

**What has been the demand for Covid-19 antibody testing?**

We were once again lucky to be an Abbott shop as we have full lab automation on Abbott Architect and had the Abbott's IgG antibody test up and running April 28. We were able to leverage that into a robust convalescent plasma collection and use program with collaboration between the New York Blood Bank and Stamford Health Department of Research. Recovered patients that test for high titers of Covid-19 antibodies are asked to donate their plasma to treat acutely ill patients. Convalescent plasma use at Stamford Health has resulted in very impressive results and favorable outcomes in the most acutely ill Covid-19 patients.

I do believe there has been an underutilization of Covid-19 antibody testing for population health studies. Large-scale seroprevalence testing, combining PCR and antibody testing, of a city or region would provide a lot of information on where we stand with this virus. I'm confounded as to why more seroprevalence studies aren't being done at the regional, state and federal levels. The focus on PCR testing in the Point Prevalence Testing strategy is short-sighted in that it does not address the population as a whole. The focus should be the antibody response in humans – not the detection of virus alone.

**Can a person get Covid-19 twice?**

Of the nearly 50 million worldwide Covid-19 cases, there have been only a few documented cases of reinfection. They are unicorns and thus reported in medical literature. Unfortunately this is the kind of information the media focuses on.

**Do you expect a resurgence of Covid-19 in Connecticut this winter?**

We are beginning to see a small increase in cases, but we are much better prepared for any potential surge than we were in the spring. Covid-19 illness in March of 2020 is certainly not Covid-19 in November 2020. We have testing, PPE, effective therapeutics, and above all experience – which all translates to much better patient outcomes. We know better what to do and what not to do.

Covid-19 patients are now being placed in the prone position and getting antivirals, steroids and less invasive oxygen therapy, and there is more caution before placing patients on ventilators. Overall, we're now seeing a 98% recovery rate for hospitalized Covid-19 patients.

In addition, we expanded our respiratory illness testing capacity and are now setting up rapid testing for Covid-19, influenza, RSV and strep B at outpatient locations in Stamford, Greenwich, Wilton and New Canaan using Veritors and Abbott ID Now.

We also continue serving as a "care partner" under the CT executive order and perform weekly Covid-19 PCR tests of residents and staff at 20 nursing homes and assisted living facilities.

Interestingly, we have tested for zero positive cases of influenza so far. This is extremely unusual for this time of year and probably a result of social distancing and masking.

**Have lab test volumes rebounded since the lows in the spring?**

Overall, including Covid-19 and non-Covid testing, our volumes are currently running at 120% of pre-pandemic levels. Most testing categories have almost fully recovered from the lows in March and April. However, pathology case volumes are currently at about 80% of year-ago levels. Some patients are reluctant to leave their homes and are deferring care. A lot of mammograms, breast imaging, Pap tests, colonoscopies and skin cancer screenings are being delayed. This has very troubling long-term consequences.

**Supply Shortages Impacting Non-Covid-19 Testing** (*cont'd from page 1*)

The American Society for Microbiology (ASM) in partnership with the Association of Supply Chain Management has been conducting an ongoing weekly survey of CLIA-certified labs since September 11. The latest survey results through early November confirmed the well-known shortage of Covid-19 molecular testing kits with 50% of the 122 surveyed labs reporting shortages.

However, the ASM survey also revealed less-publicized shortages for microbiology tests. For example, 30% of surveyed labs said they were experiencing test supply shortages for routine bacteria testing to detect infections like strep throat, bronchitis and urinary tract infections.

The most worrying test supply shortage is for sexually transmitted infections (STIs), including HIV/AIDS, chlamydia and gonorrhea, and HPV testing, for which 43% of surveyed labs reported shortages.

“In my opinion, the most concerning non-Covid shortage is that of testing kits and collection devices for sexually transmitted infections like gonorrhea and chlamydia. We had to cease testing males for STIs due to shortages, so physicians had to rely on empiric therapy when indicated. Unfortunately, many STIs can be asymptomatic, so a provider may not know to treat a patient without testing. This is definitely a step backwards in the efforts to treat STIs and curb their transmission,” according to Melissa Miller, PhD, who is chair of ASM’s Clinical and Public Health Microbiology Committee and Director of the Clinical Microbiology Laboratory at UNC School of Medicine (Chapel Hill, NC).

**Non-Covid-19 Laboratory Test Supply Shortages**

<i>Test Category</i>	<i>Avg. % of Labs with Shortages</i>	<i>Avg. # Days of Testing Remaining with Current Supplies</i>
Routine Bacteria Testing (e.g. strep throat, pneumonia, bronchitis and urinary tract infections)	30%	20 days
Routine Mycobacteria Testing (e.g. tuberculosis (TB), Buruli ulcer and pulmonary nontuberculous mycobacterial disease)	29%	30 days
Routine Fungal Testing (from superficial, localized skin conditions to deeper tissue infections to serious lung, blood (septicemia) or systemic diseases)	50%	10 days
Routine Sexually Transmitted Infections (STI) Testing (includes HIV/AIDS, chlamydia, gonorrhea, pelvic inflammatory disease (PID), genital warts and human papillomavirus (HPV), genital herpes (HSV-1, HSV-2) and syphilis)	43%	15 days

Source: American Society for Microbiology

## Spotlight Interview With Ortho's Chockalingam Palaniappan

Ortho Clinical Diagnostics (Raritan, NJ) received Emergency Use Notification from the FDA for its VITROS SARS-CoV-2 antigen test for nasopharyngeal swab samples in early November. *Laboratory Economics* recently spoke to Ortho's Chief Innovation Officer Chockalingam "Palani" Palaniappan, PhD, for insight into the benefits of Covid-19 antigen testing versus PCR testing.



### **How many VITROS analyzers are currently placed in the United States?**

OCD has 1,500 VITROS instruments placed at 1,000 locations, primarily hospital labs, in the United States. Each VITROS is capable of processing up to 130 antigen samples per hour. So hypothetically, VITROS analyzers could potentially perform more than four million Covid-19 antigen tests per day.

### **Where is the test manufactured and are there any chemical or other input shortages that could limit production?**

At Ortho's Global Center of Excellence in Rochester, New York and a manufacturing facility in Pencoed, Wales. At this time, we do not foresee any shortages which will impact production.

### **How does the accuracy of Ortho's antigen test compare with Covid-19 PCR testing?**

Compared to PCR, Ortho's test is better able to identify patients with Covid-19 who are infectious because it has 100% sensitivity and 99.2% specificity on samples with a PCR cycle threshold level (a measure of viral load) of less than 34.

One of the drawbacks of Covid-19 PCR testing is that it's so highly sensitive that it can detect dead virus remnant fragments in patients who have recently had the virus, recovered and are no longer infectious. Studies have shown that patient samples with PCR cycle threshold levels at 30 to 33 or more carry little or no live virus.

We know that the Covid-19 virus is active in patients for about 7-14 days after initial infection. But non-infectious dead virus particles can linger in patients for another 1-3 weeks. So PCR testing may be placing unnecessary anxiety and quarantine restrictions on a portion of patients that test positive for dead virus fragments.

### **So why don't labs performing Covid-19 PCR testing report cases with a cycle threshold count of <34 as positive, and report those with cycle threshold count of >34 as negative?**

Increasingly there are publications from leading epidemiologists asking for testing reports to include CT values.

### **What are the ideal situations for Covid-19 antigen testing?**

Any place where regular en masse testing is needed, such as high schools, universities, sports teams, churches, airports, etcetera. I'd also point out that antigen-based tests are significantly less expensive than PCR tests. [*Laboratory Economics* notes that Medicare currently reimburses \$45 for Covid-19 antigen tests versus \$100 for Covid-19 PCR tests.]

### **At what point does it make sense to stop or reduce Covid-19 diagnostic testing? For example, when a population averages less than 2% positivity, or <1%, or <0.5%?**

I don't know the correct answer to that. And right now, with cases and hospitalizations rising in the United States, we are far from that situation.

### **Can a person get Covid-19 twice?**

That's very unlikely. Covid-19, like other viruses, triggers an immune response that the body remembers and can be reactivated if the virus is encountered again. The question is how long does immunity last, six months, one year, or longer? Time will tell.

## Volume Surge Expected For High-Priced Covid-19 Test Panels

With the flu season underway, more test panels are becoming available that test for Covid-19 plus other respiratory viruses, including influenza A/B and respiratory syncytial virus (RSV). Labs have begun to submit the combo PCR tests codes for Covid-19, although volume is nominal at this stage, notes Lale White, Chief Executive at XIFIN Inc. (San Diego, CA).

The AMA has issued new CPT codes for Covid-19 PCR-based test panels (87636 & 87637) and Medicare contractors have set rates for both of these codes at \$142.63 by crosswalking to the existing code 87631 (respiratory virus detection, 3-5 targets).

In addition, several Proprietary Laboratory Analyses (PLA) codes (e.g., 0223U, 0202U and 0225U) have been issued for larger Covid-19 test panels that include up to 22 pathogen targets. Medicare contractors have set rates for these codes at \$416.78 by crosswalking to the existing code 87507 (infectious agent detection, 12-25 targets).

There are currently an average of 1.5 million Covid-19 PCR tests being performed each day in the United States at cost of roughly \$150 million per day, or \$50+ billion annualized. A transition toward combo test panels reimbursed at \$142-\$417 per panel could potentially push the annualized market to more than \$100 billion. That would exceed the total U.S. market for all non-Covid clinical lab and pathology testing.

In June 2020, the Office of Inspector General (OIG) communicated its fear that many labs are performing medically unnecessary add-on tests when responding to orders for Covid-19. The OIG has added an analysis for potential fraud and abuse with Covid-19 add-on testing to its work plan, notes Charles Root, PhD, President of CodeMap LLC.

### Medicare Rates for Covid-19 Testing

Code	Short Description	Rate
U0002	Covid-19 diagnostic test, any technique (low-throughput), non-CDC	\$51.31
87635	Covid-19 PCR-based diagnostic test (low throughput)	\$51.31
U0003	Covid-19 PCR-based diagnostic test (high-throughput)	\$100/\$75*
U0004	Covid-19 diagnostic test, any technique (high-throughput)	\$100/\$75*
U0005	Add-on payment for high-throughput Covid-19 testing (U0003 or U0004) completed within two calendar days from date and time of specimen pickup.	\$25.00**
87636	Covid-19 plus influenza virus types A and B (PCR-based testing)	\$142.63
87637	Covid-19, influenza virus types A and B plus respiratory syncytial virus (PCR-based testing)	\$142.63
86328	Covid-19 antibody(ies) single-step method (i.e., point-of-care testing)	\$45.23
86769	Covid-19 antibody testing with multi-step methods (i.e., laboratory-based). May be submitted separately for IgG, IgM and IgA.	\$42.13
87426	Covid-19 antigen detection by immunoassay technique (i.e., laboratory-based)	\$45.23
87428	Covid-19 antigen detection plus influenza virus types A and B by immunoassay technique (i.e., laboratory-based)	NA
87811	Covid-19 antigen detection by immunoassay with direct optical (i.e., point-of-care testing)	\$42.13
G2023	Specimen collection for Covid-19 from homebound or non-hospital inpatients, any specimen source	\$23.46
G2024	Specimen collection for Covid-19 from patient in nursing home or by a laboratory on behalf of a home health agency, any specimen source	\$25.46

\*Reimbursement rate drops to \$75 for U0003 & U0004 effective January 1, 2021.

\*\*U0005 is effective January 1, 2021.

Source: Novitas, CodeMap, XIFIN and CMS

## Spotlight Interview with ACLA President Julie Khani

The American Clinical Laboratory Association (ACLA), which represents leading laboratories across the country, has been at the forefront of advocating for clinical labs in matters of reimbursement, regulation and legislation. *Laboratory Economics* recently asked ACLA President Julie Khani about the association's priorities right now.



### What would the lab industry like to see in any future Covid-19-related legislation?

Patients need certainty that their Covid-19 tests will be covered. This is a common-sense cause with rare bipartisan support. In recent weeks, a group of 54 bipartisan lawmakers in the House of Representatives and a group of eight Republican senators sent letters to [Health and Human Services] Secretary Azar expressing concerns over recent coverage denials from health plans for Covid-19 testing. In addition, congressional leaders recently announced plans to dramatically expand free testing for lawmakers, an action we strongly support. As cases spike across the country, we urge elected leaders to extend the same safeguard to the constituents they serve. In addition, ending the harmful PAMA cuts remains a top priority for our members and the millions of patients we serve.

### What are your thoughts on the new \$75 Medicare rate (effective January 1) for Covid-19 PCR tests that exceed a two-day turnaround time?

The latest change from CMS raises red flags for a number of reasons, primarily that payment cuts don't actually address the root causes of delayed turnaround times. Turnaround times are driven largely by fluctuations in demand and access to critical supplies. From the earliest days of this pandemic, ACLA members have been doing everything we can to develop and scale up accurate and reliable testing as quickly as possible. We remain wholly focused on that mission.

### Where does the PAMA lawsuit stand today?

ACLA's ongoing legal challenge (*ACLA vs. Azar*) is still pending and currently under review by the U.S. District Court for the District of Columbia.

### Do you have any sense that CMS has become more sympathetic to a settlement since labs have played such an important role in the pandemic?

What I can say is that the effects of PAMA are in plain sight. This pandemic exposed a truth that lab directors have been warning us about for years: spiraling, year-over-year, across-the-board cuts to Medicare reimbursement left labs with razor thin margins and significant challenges when it came to scaling up. As a consequence, some labs were left in the untenable position of having to make difficult choices about downsizing or eliminating back-up supply chains.

### What is your opinion on the recent decision to keep the FDA out of regulating lab-developed tests?

Labs providing vital testing services during the pandemic need clarity and certainty about how those services are regulated. Advancing common sense, comprehensive diagnostic reform legislation is critical to our ability to tackle the most challenging and complex health needs of the country. It's important that the new Congress prioritize advancing a modernized, diagnostic-specific statutory framework.

### Any thoughts on how the coming President Biden Administration might affect healthcare and labs?

ACLA members stand ready to support the Biden Administration as it confronts the greatest public health threat in a century. We commend the Biden Administration for making it a top priority to ensure that all Americans have access to accurate and reliable testing. ACLA agrees that patients need certainty that their Covid-19 tests will be covered. This is a common-sense cause with bipartisan support.



## LabCorp Completes Several Hospital Lab Deals

LabCorp has acquired the clinical lab outreach business of CaroMont Health (Gastonia, NC). LabCorp plans to transition all of CaroMont's routine clinical lab outreach tests to its Atlantic Division workflow in Burlington, North Carolina. CaroMont's flagship hospital is 383-bed CaroMont Regional Medical Center. Its clinical lab outreach business generates roughly \$2 million per year in Medicare CLFS revenue, according to its Hospital Cost Report for the fiscal year ended June 30, 2019. *Laboratory Economics* estimates that CaroMont's overall annual clinical lab outreach revenue is roughly \$10 million.

### Franciscan Missionaries of Our Lady Health System

The CaroMont deal follows LabCorp's purchase of Franciscan Missionaries of Our Lady Health System's clinical lab outreach business in June. LabCorp will also provide reference testing services for FMOLHS' hospitals in Louisiana and Mississippi. The flagship hospital at FMOLHS is 876-bed Our Lady of the Lake Regional Medical Center (Baton Rouge, LA). Its clinical lab outreach business generates roughly \$2.7 million per year in Medicare CLFS revenue, according to its Hospital Cost Report for the fiscal year ended June 30, 2019. *Laboratory Economics* estimates that FMOLHS's overall annual clinical lab outreach revenue is roughly \$15 million.

### University of Miami Health System

LabCorp and University of Miami Health System (UHealth) finalized an agreement under which LabCorp will provide clinical lab outreach and reference testing services to the UHealth network. The service agreement follows a recent contract LabCorp won to help expand on-site Covid-19 testing at UHealth's labs and through LabCorp reference testing.

UHealth's current lab outreach business generates roughly \$500,000 per year in Medicare CLFS revenue, according to its Hospital Cost Report for the fiscal year ended May 31, 2019. *Laboratory Economics* estimates that UHealth's overall annual clinical lab outreach revenue is less than \$5 million.

UHealth will continue to provide all existing inpatient lab testing services through its three hospital-based labs. UHealth's largest hospital is the 524-bed UHealth Tower (formerly named University of Miami Hospital), which has an annual lab department budget of \$51 million.

### Rush University System for Health

In addition, LabCorp won a clinical lab service agreement with Rush University System for Health (Chicago, IL). The Rush System includes three hospitals, including 697-bed Rush University Medical Center, 210-bed Rush-Copley Medical Center and 201-bed Rush Oak Park Hospital.

### Infirmiry Health

Finally, LabCorp won a clinical lab service agreement with Infirmiry Health (Mobile, AL). Infirmiry Health includes three hospitals—the largest is the 654-bed Mobile Infirmiry Medical Center.

## New LabCorp Hospital Lab Agreements

Hospital Name	Location	# Beds	Total Lab Dept. Budget 2019	Medicare Part B CLFS Payments 2019
CaroMont Regional Medical Center	Gastonia, NC	383	\$22,016,145	\$2,025,768
Our Lady of the Lake Regional Medical Center	Baton Rouge, LA	876	\$63,219,758	\$2,662,709
UHealth Tower	Miami, FL	524	\$50,867,169	\$478,224
Rush University Medical Center	Chicago, IL	697	\$99,571,365	\$1,366,676
Mobile Infirmiry Medical Center	Mobile, AL	654	\$30,870,961	\$390,595

Source: Laboratory Economics from Hospital Cost Reports and American Health Directory

## Top 25 Hospital Outreach Labs for 2019

The table below lists the top 25 hospital-based outreach labs as measured by Medicare Part B CLFS and Physician Fee Schedule anatomic pathology test payments in 2019. Overall, the top 25 hospital labs had \$169 million in Part B payments, which was down approximately 8% from 2018 due to the PAMA-related CLFS rate cuts.

### Top 25 Hospital Outreach Labs for 2019 by Medicare Part B Payments

Hospital Name	Location	# Beds	Medicare Part B CLFS Payments 2019	Medicare Part B Anatomic Pathology Payments 2019	Total Part B CLFS & AP Payments 2019
Northwestern Medicine Central DuPage Hospital	Winfield, IL	395	\$14,877,709	\$584,980	\$15,462,689
New York Presbyterian/Weill Cornell Medical Ctr	New York, NY	2,670	13,888,040	406,455	14,294,495
Carolinas Medical Center	Charlotte, NC	1,269	9,332,270	770,916	10,103,186
Northwestern Memorial Hospital	Chicago, IL	908	7,751,457	925,164	8,676,621
Beaumont Hospital-Royal Oak	Royal Oak, MI	1,098	7,318,818	227,740	7,546,558
The Cleveland Clinic	Cleveland, OH	1,310	6,935,795	278,676	7,214,471
Ascension Saint John Hospital	Detroit, MI	612	6,822,760	105,936	6,928,696
Eisenhower Medical Center	Rancho Mirage, CA	368	6,358,488	197,832	6,556,320
Sentara Norfolk General Hospital	Norfolk, VA	527	5,969,430	244,200	6,213,630
Evanston Hospital	Evanston, IL	750	5,864,424	313,350	6,177,774
Hospital of the University of Pennsylvania	Philadelphia, PA	806	3,841,530	2,307,360	6,148,890
Massachusetts General Hospital	Boston, MA	1,017	4,498,220	1,386,210	5,884,430
The Univ of Texas M. D. Anderson Cancer Ctr	Houston, TX	670	2,950,682	2,873,808	5,824,490
Cedars-Sinai Medical Center	Los Angeles, CA	880	5,686,608	116,835	5,803,443
Sarasota Memorial Hospital	Sarasota, FL	811	5,466,440	16,051	5,482,491
Morton Plant Hospital	Clearwater, FL	678	5,258,286	182,442	5,440,728
Baystate Medical Center	Springfield, MA	733	5,030,606	348,642	5,379,248
Oroville Hospital	Oroville, CA	153	5,149,730	120,106	5,269,836
Cleveland Clinic Martin Medical Center	Stuart, FL	521	5,153,490	77,112	5,230,602
UC Davis Medical Center	Sacramento, CA	617	4,296,280	787,780	5,084,060
NYU Langone Tisch Hospital	New York, NY	1,629	4,359,887	517,356	4,877,243
Charlton Memorial Hospital	Fall River, MA	867	4,593,498	239,676	4,833,174
Morristown Medical Center	Morristown, NJ	669	4,665,204	107,430	4,772,634
Sparrow Hospital	Lansing, MI	632	4,509,816	247,984	4,757,800
OhioHealth Riverside Methodist Hospital	Columbus, OH	734	4,451,103	268,452	4,719,555
Totals for Top 25 Hospital Outreach Labs		21,324	\$155,030,571	\$13,652,493	\$168,683,064

Note: The above list does not include hospital-owned independent labs that bill through their own NPI, such as ACL Laboratories, ACM Medical Labs, DMC University Labs, Health Network Labs, Northwell Health Labs, Scripps Health, Sutter Valley Medical Foundation, Tricore Reference Labs, et al.

Source: *Laboratory Economics* from Hospital Cost Reports and American Health Directory

## Biodesix Raises \$72 Million From IPO

**B**iodesix Inc. (Boulder, CO) raised gross proceeds of \$72 million from an IPO of four million shares priced at \$18 on October 28. Morgan Stanley, William Blair, Canaccord Genuity and BTIG were the underwriters for the IPO. Net proceeds to Biodesix were \$63 million after deducting investment banking fees and commissions and legal expenses. Biodesix expects to use the funds to commercialize its liquid-biopsy tests and for research and development of new tests.

Biodesix, which has 154 employees, currently markets four proprietary liquid-biopsy tests for lung cancer performed at its CLIA-certified labs in Boulder, Colorado (30,000 sq. ft.) and De Soto, Kansas (9,000 sq. ft.). The company's diagnostic tests are marketed primarily to pulmonologists, oncologists, cancer centers and nodule clinics. Since inception in 2005, Biodesix has performed over 245,000 tests. The company's diagnostic tests include:

- **Nodify XL2:** A blood-based test designed to rule out malignancy in low-to-moderate-risk lung nodules—with the goal of sparing patients a lung biopsy. The test has been designated by Medicare as an Advanced Diagnostic Laboratory Test (ADLT) under the code 0080U at a reimbursement rate of \$3,520.
- **Nodify CDT:** A blood-based test designed to help physicians identify patients with lung nodules at high risk of lung cancer. The Nodify CDT test is billed using the unlisted MAAA code 81599.
- **VeriStrat:** A blood-based immune profiling test that provides a personalized view of each patient's immune response to their lung cancer and helps inform physicians whether their patient has a more aggressive cancer. VeriStrat has been designated by Medicare as an Advanced Diagnostic Laboratory Test (ADLT) under the code 81538 at a reimbursement rate of \$2,871.
- **GeneStrat:** A blood-based mutation test for genotyping tumors of patients with advanced non-small cell lung cancer (NSCLC). Biodesix uses four CPT codes, 81479 (unlisted molecular pathology procedure), 81210 (BRAF), 81235 (EGFR), and 81275 (KRAS), for billing GeneStrat.

In addition, Biodesix began Covid-19 PCR testing at its Boulder lab using Bio-Rad's Covid-19 Droplet Digital PCR test in early April and began antibody testing in mid-May.

Biodesix reported a net loss of \$18 million for the six months ended June 30, 2020, compared with a net loss of \$14.6 million for the same period a year earlier. Total six-month revenue was down 24% to \$9.3 million, including clinical diagnostics test revenue of \$7.2 million, down 19%, and biopharmaceutical/clinical trial testing revenue of \$2.1 million, down 38%. The company attributed the revenue decline to a slowdown in non-COVID-19 testing for both its clinical and biopharmaceutical testing services due to the Covid-19 pandemic. For the six months ended June 30, 2020, Medicare accounted for 60% of Biodesix's diagnostic test revenue.

Since being founded in 2005, Biodesix has accumulated losses of \$249 million.

At its IPO price of \$18 per share, Biodesix has a market capitalization of \$474 million. Biodesix's Chairman John Patience has an 18% stake in the company, while board member Jack Schuler has 29% ownership.

## Lab Stocks Have Jumped 56% Year To Date

Twenty two lab stocks have risen by an unweighted average of 56% year to date through November 13. In comparison, the S&P 500 Index is up 11% so far this year. The top-performing lab stocks thus far in 2020 are Aspira Women's Health (formerly named Vermillion), up 509%; Invitae is up 192%; and Opko Health is up 171%. Shares of LabCorp are up 18%, while Quest Diagnostics is up 14%.

Company (ticker)	Stock Price 10/16/20	Stock Price 12/31/19	2020 Price Change	Enterprise Value (\$ mill)	Enterpr Value/ Revenue	Enterpr Value/ EBITDA
LabCorp (LH)	\$199.59	\$169.17	18%	\$25,460	2.1	12.2
Quest Diagnostics (DGX)	121.52	106.79	14%	19,920	2.4	10.1
Sonic Healthcare (SHL.AX)*	34.30	28.75	19%	19,770	2.9	14.0
Exact Sciences (EXAS)	122.71	92.48	33%	18,890	14.3	NA
Guardant Health (GH)	116.16	78.14	49%	10,630	39.2	NA
Invitae (NVT)	47.02	16.13	192%	8,280	33.7	NA
Natera (NTRA)	82.81	33.69	146%	6,590	18.2	NA
NeoGenomics (NEO)	41.77	29.25	43%	4,570	10.8	232.2
Opko Health (OPK)	3.99	1.47	171%	2,740	2.4	668.5
CareDx (CDNA)	54.49	21.57	153%	2,490	14.7	NA
Veracyte (VCYT)	46.63	27.92	67%	2,370	21.0	NA
Myriad Genetics (MYGN)	16.75	27.23	-38%	1,390	2.3	NA
Castle Biosciences (CSTL)	50.36	34.37	47%	842	13.4	NA
Aspira Women's Hlth (AWH)	4.93	0.81	509%	454	99.6	NA
Biodesix (BDSX)	11.32	18.00	-37%	342	15.9	NA
Progenity (PROG)	4.47	15.00	-70%	219	2.7	NA
DermTech Inc. (DMTK)	13.41	12.40	8%	211	39.5	NA
Exagen (XGN)	14.79	25.40	-42%	158	4.0	NA
Enzo Biochem (ENZ)	1.99	2.63	-24%	80	1.1	NA
Biocept (BIOC)	4.78	2.90	65%	62	10.9	NA
Psychemedics (PMD)	4.13	9.15	-55%	29	1.2	NA
Interpace Biosciences (IDXG)	3.10	5.00	-38%	6	0.2	NA
Unweighted Averages			56%	\$125,502	16.0	187.4

\*Sonic Healthcare's figures are in Australian dollars

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

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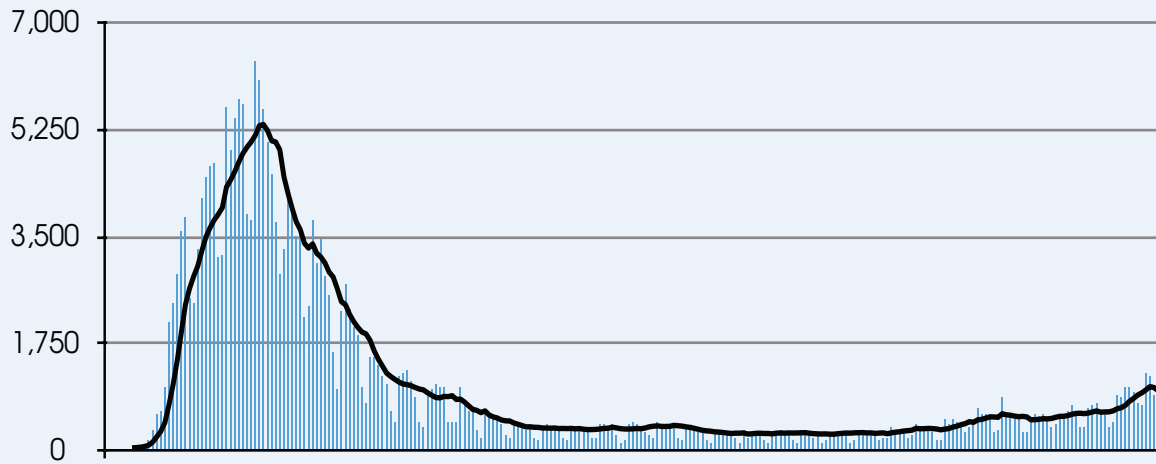
**Covid-19 Statistics for 61 Countries (November 15, 2020)**

<i>Country</i>	<i>Population (millions)</i>	<i>Median Age</i>	<i>% Urban Population</i>	<i>% Pop Obese</i>	<i>Total Cases</i>	<i>Total Deaths</i>	<i>Deaths/ 1M Pop</i>
Belgium	11.6	42	98%	22%	531,280	14,303	1,232
Peru	33.0	31	78%	20%	934,899	35,177	1,061
Spain	46.8	45	80%	24%	1,492,608	40,769	872
Argentina	45.4	32	92%	28%	1,304,846	35,307	779
Brazil	212.7	33	88%	22%	5,848,959	165,673	777
Chile	19.2	34	88%	28%	529,676	14,777	771
United Kingdom	67.9	40	83%	28%	1,344,356	51,766	761
Mexico	129.1	29	84%	29%	1,003,253	98,259	759
United States	331.7	38	82%	42%	11,229,554	251,268	757
Bolivia	11.7	26	69%	20%	143,181	8,841	754
Italy	60.5	47	71%	20%	1,144,552	44,683	739
Ecuador	17.7	28	64%	20%	179,627	12,997	733
France	65.3	42	82%	22%	1,954,599	44,246	677
Columbia	51.0	31	81%	21%	1,191,004	33,829	662
Panama	4.3	30	68%	23%	145,309	2,867	661
Sweden	10.1	41	88%	21%	177,355	6,164	609
Netherlands	17.1	43	92%	21%	442,458	8,443	492
Iran	83.7	32	76%	26%	762,068	41,493	492
Ireland	5.0	38	63%	25%	67,526	1,978	399
Bahamas	0.395	32	86%	32%	7,163	155	393
Switzerland	8.7	43	74%	20%	257,135	3,351	386
South Africa	59.6	28	67%	28%	749,182	20,206	339
Israel	8.6	30	93%	26%	323,503	2,732	297
Canada	37.7	41	81%	29%	291,931	10,891	288
Poland	37.8	40	60%	23%	712,972	10,348	274
Russia	145.9	40	74%	23%	1,925,825	33,186	227
Ukraine	43.6	41	69%	24%	535,857	9,603	220
Guatemala	18.0	23	52%	21%	114,719	3,920	217
Austria	9.0	44	57%	20%	203,956	1,829	203
Kuwait	4.3	37	100%	38%	136,840	838	195
Saudi Arabia	35.0	32	84%	35%	352,950	5,641	161
Germany	83.9	46	76%	22%	788,899	12,619	150
Turkey	84.5	32	76%	32%	411,055	11,418	135
Denmark	5.8	42	88%	20%	61,078	757	131
Morocco	37.0	30	64%	26%	288,211	4,697	127
Greece	10.4	45	85%	25%	72,510	1,035	99
India	1,385.0	28	35%	4%	8,816,401	129,696	94
Jamaica	3.0	31	55%	25%	9,780	229	77

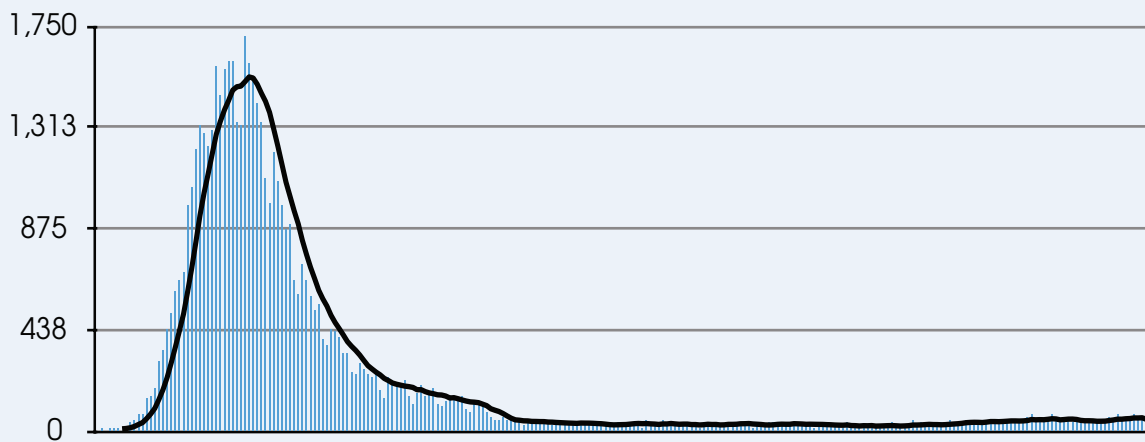
Country	Population (millions)	Median Age	% Urban Population	% Pop Obese	Total Cases	Total Deaths	Deaths/1M Pop
Iceland	0.342	38	94%	22%	5,186	25	73
Philippines	110.0	26	47%	6%	407,838	7,832	71
Finland	5.5	43	86%	22%	19,315	369	67
Egypt	102.3	25	43%	32%	110,547	6,442	63
Indonesia	274.6	30	56%	7%	467,113	15,211	55
Norway	5.4	40	83%	23%	28,434	294	54
Bangladesh	165.2	28	39%	4%	432,333	6,194	37
Australia	25.6	38	86%	29%	27,728	907	35
Pakistan	222.5	23	35%	9%	356,904	7,141	32
Sudan	44.2	20	35%	7%	14,626	1,116	25
Kenya	54.2	20	28%	7%	69,273	1,228	23
Yemen	30.0	20	38%	17%	2,072	605	20
Japan	126.3	48	92%	4%	114,983	1,880	15
Ethiopia	116.0	19	21%	5%	102,321	1,565	13
South Korea	51.3	44	80%	5%	28,546	493	10
Malaysia	32.5	30	78%	16%	47,417	309	10
Nigeria	206.1	18	52%	9%	64,996	1,163	6
Singapore	5.9	42	99%	6%	58,119	28	5
New Zealand	5.0	38	87%	31%	2,001	25	5
Ivory Coast	26.6	19	51%	10%	20,945	127	5
China	1,439.3	38	61%	6%	86,338	4,634	3
Thailand	69.9	40	51%	10%	3,874	60	1
Vietnam	97.7	33	37%	2%	1,281	35	0.4
Avg. for High Median Age Countries (>35)	94.4	42	80%	22%	23,745,815	556,792	310
Avg. for Low Median Age Countries (<35)	116.3	28	61%	19%	25,213,452	676,882	302
Avg. for High Obesity Countries (>20%)	46.5	36	78%	25%	37,863,887	1,054,357	423
Avg. for Low Obesity Countries (<20%)	247.6	29	52%	7%	540,160	11,203	24
Avg. for High Urban Pop Countries (>80%)	49.5	38	87%	24%	28,580,235	790,874	407
Avg. for Low Urban Pop Countries (<80%)	150.7	31	56%	17%	20,379,032	442,800	225
<b>Total Worldwide</b>	<b>7,825.6</b>	<b>31</b>	<b>56%</b>	<b>13%</b>	<b>54,458,016</b>	<b>1,320,350</b>	<b>169</b>

Source: World Health Organization and Worldometer (November 15, 2020)

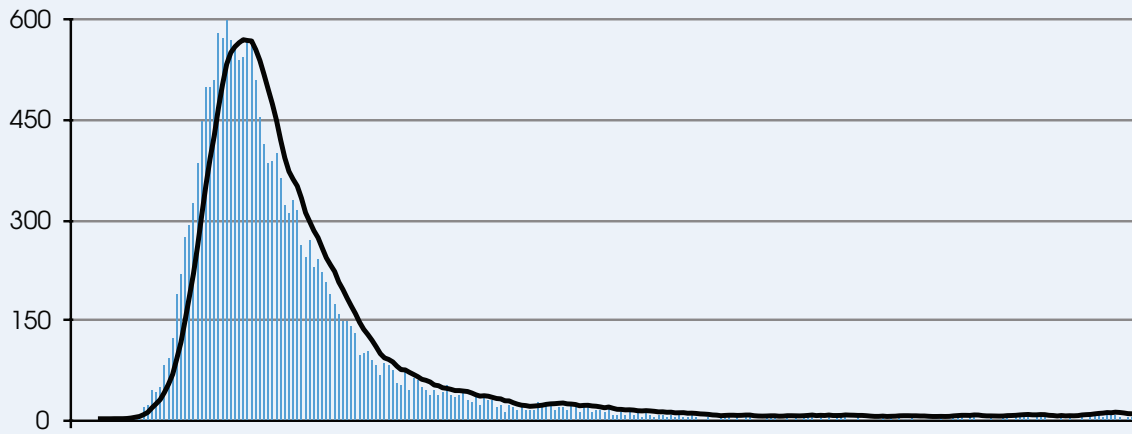
**New York City Daily New Cases of Covid-19 with 7-Day Moving Avg. (March 1 through Nov. 12, 2020)**



**NYC Daily New Hospitalizations from Covid-19 with 7-Day Moving Avg. (March 1 through Nov. 12, 2020)**



**New York City Daily Deaths from Covid-19 with 7-Day Moving Avg. (March 1 through Nov. 12, 2020)**



Source: NYC Department of Health and Mental Hygiene