# LABORATORY

# ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

# UnitedHealthcare Requiring Hospital Outreach Labs To Contract As Independent Reference Labs

UnitedHealthcare (UHC) says that hospital labs cannot bill for non-patient outreach tests under their hospital's facility participation agreement.

UHC has had this policy in effect for more than one year. What's new is that UHC now appears ready to actually enforce it. Effective May 1, 2020, non-patient lab test claims submitted by hospital outreach labs will be denied if billed under the hospital's facility participation agreement, according to UHC's Network Bulletin for February 2020. UHC says that hospital outreach labs must get credentialed and contracted as an independent reference lab in order to get their non-patient lab test claims paid.

Enforcement of this policy could potentially eliminate many hospital outreach labs from UHC's network and dramatically reduce reimbursement for those labs that do get contracted and paid under independent reference lab fee schedules, notes Scott Liff, President and CEO of Kellison & Company (Cleveland, OH). *Continued on page 4*.

# **Putting The Coronavirus Into Perspective**

The number of coronavirus (Covid-19) cases continues to rapidly rise in the United States. As of this morning (March 16), there have been 3,774 cases and 69 deaths from Covid-19 in the United States, according to the Johns Hopkins University Coronavirus Resource Center, which has the most up-to-date Covid-19 case statistics.

The S&P 500 Index has entered bear market territory, the Federal Reserve has cut short-term interests and President Trump has declared a national emergency and signed off on tens of billions of dollars of new Covid-19 relief spending. In addition, 40 states in the country have declared a state of emergency and West Virginia is the only state that has not reported at least one Covid-19 case. Furthermore, medical supply makers like 3M say they can't keep up with the spike in demand for surgical face masks, and hoarding is emptying store shelves of toilet paper, thermometers, bread and canned foods.

But is the reaction to Covid-19 reasonable in relation to the actual risks related to this new respiratory virus? *Continued on page 2*.

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#### Putting The Coronavirus Into Perspective (cont'd from p. 1)

Part of the reason why the media, politicians and the public seem to have lost perspective over Covid-19 might be because it's a new virus with no vaccine and very little immunity built up in the human population. In comparison to the common flu, Covid-19 is more contagious and has a significantly higher fatality rate (currently estimated at ~1% versus 0.1% for common flu). Even so, Laboratory Economics can't help but think that there's been an overreaction to Covid-19, and that the consequences of "pandemic panic" may eclipse the actual harm caused by the virus itself (see page 11).

Smaller-scale panics have occurred with other novel viruses, like SARS, Ebola and Swine Flu. The SARS virus of 2002-2003 had 27 U.S. cases and zero deaths. Two people contracted the Ebola Virus in the United States in 2014. Both were nurses who had treated an Ebola patient from Africa; both recovered.

The closest parallel to Covid-19 in recent history might be the outbreak of a strain of influenza (H1N1) that came to be called Swine Flu. From April 2009 through April 2010, the Swine Flu

infected approximately 61 million Americans, causing 274,000 hospitalizations and 12,469 deaths, according to the CDC. The experience of the Swine Flu outbreak suggests that there could be millions of new Covid-19 cases in the U.S. reported and thousands of deaths in the next few months.

In comparison, the 2017-2018 flu season was particularly deadly with approxi-

#### A Comparison of Various Outbreaks (U.S. only)

Outbreak Name	Reported Cases	Hospitalizations	Deaths
SARS Virus, 2002-2003	8	NA	0
Swine Flu, 2009-2010	60,800,000	274,000	12,469
MERS, 2012-2014	2	2	0
Ebola Virus, 2014	2	2	0
Zika Virus, 2016	5,168	NA	0
Common Flu, 2017-2018	44,800,000	808,100	61,000
Common Flu, 2019-2020*	36,000,000+	370,000+	22,000+
Covid-19, 2019-2020**	3,774	NA	69

<sup>\*</sup>CDC estimates covering October 1, 2019 through March 7, 2020

Source: CDC and Johns Hopkins University

mately 45 million U.S. cases that resulted in 808,000 hospitalizations and 61,000 deaths, according to the CDC. Despite its severity, that year's flu garnered little attention.

More than 22,000 Americans have already died from the common flu in the current 2019-2020 season. In fact, the CDC's statistics for the past 10 years show that an average of 37,000 Americans die from the common flu each year.

#### The Need for Nursing Home Labs

Being elderly and having other illnesses, greatly increases the risk of dying from Covid-19. Nearly all of the Covid-19 deaths in the U.S. have been among the elderly (average age ~80), including 27 deaths at one particular nursing home near Seattle. So far, the CDC and state public health labs have performed most Covid-19 testing. The nation's largest reference labs, including ARUP, BioReference, LabCorp, Mayo, Quest and Sonic, met with Vice President Pence and the White House's Coronavirus Task Force on March 4.

It's ironic that no labs devoted to serving nursing home patients were present at the White House meeting. These labs have the existing systems in place for collecting and transporting specimens from the population most vulnerable to Covid-19.

#### **Projected Covid-19 Test Volumes**

The big lab companies, specialty labs and hospitals began introducing laboratory-developed tests (LDTs) for Covid-19 on March 9. As of March 15, more than 20 private labs and hospitals were

<sup>\*\*</sup>Johns Hopkins University through morning of March 16

offering Covid-19 testing, including Opko's BioReference Labs which is collecting specimens from a drive-through facility in partnership with the New York State Department of Health. The drive-through facility is in New Rochelle, NY, and is collecting specimens from residents in the city who have been quarantined already. The drive-through sample collection is by appointment only, according to Governor Andrew Cuomo.

CMS has announced new codes for Covid-19 testing for labs that use the CDC's test kit (U0001) and for labs that create their own LDTs (U0002). Medicare claims processing systems will be able to accept these codes starting on April 1 for dates of service on or after February 4. Medicare Contractors (MACs) have set reimbursement at \$35.91 for the test kit (U0001) and \$51.31 for the LDT (U0002).

Private insurers are likely to discount their reimbursement below the new Medicare rates. Given that the window for testing might be small—the flu season is almost over—testing volumes performed by any one particular commercial lab or hospital may not wind up being significant (<10 million total tests/ 20+ lab companies and hospitals).

Meanwhile, anecdotal evidence suggests that testing volumes for rapid flu tests and respiratory virus panels are skyrocketing. Physicians are ordering these tests to rule out Covid-19. Rapid flu tests (CPT 87804; \$16.55) are mostly performed by physician-office-based labs. Independent labs per-

forming the highest volume of respiratory virus panels (CPT 87631-87634) include Genesis Molecular Diagnostics (Torrance, CA), Corona Pathology (Burbank, CA) and Diatherix Eurofins (Huntsville, AL).

Finally, worry over contracting Covid-19 may lead some people to stay at home and cancel or delay regular wellness visits to their doctor. This may cause labs to see a temporary decline in

Labs Performing High Volume of Respiratory Virus Testing

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Laboratory Name	Location	Part B Test Volume		
Genesis Molecular Diagnostics	Torrance, CA	13,644		
Corona Pathology	Burbank, CA	7,746		
Diatherix Eurofins Labs	Huntsville, AL	4,698		
Privilege Dx Medical Labs	Toluca, CA	2,667		
Chabado Genomics Inc.	Torrance, CA	2,073		
Sunrise Clinical Labs	Montrose, CA	1,788		
High Precision Diagnostics	Ontario, CA	1,573		
Gamma Healthcare	Poplar Bluff, MO	1,392		
One Lab LLC.	Inglewood, CA	1,327		
Quest Diagnostics	National	946		
Northwell Health Labs	Long Island, NY	936		
Health Network Labs	Allentown, PA	875		
LabCorp	National	865		
North Central Florida Neurodiagnostic Services	Alachua, FL	854		
Total Diagnostix	Memphis, TN	853		

Source: 2017 Medicare Part B carrier test volume for CPT 87502 and 87631-87634

routine screening tests like lipid panels, PSA tests and Pap & HPV tests.

#### What Happens when the Flu Season Ends?

Viral respiratory illnesses, such as the common flu, generally survive better in colder, drier weather, and therefore infect more people during the winter. The flu season in the U.S. usually gets into full swing in December, peaks in February and ends in March. Some experts are hopeful that similar to the common flu, Covid-19 will not be transmitted as easily in the warmer, more humid spring and summer temperatures.



#### UHC Requiring Hospital Outreach Labs (cont'd from page 1)

Liff says that the policy affects nearly all hospitals that provide non-patient lab outreach testing to UnitedHealthcare. The exception is roughly 100 hospital-owned independent labs (e.g., ACL Labs, Northwell Health, Tricore, et al.) that bill under their own distinct NPI and are already treated like independent reference labs with separate contractual agreements in place. In addition, a handful of the nation's largest hospital-based outreach labs without their own unique NPI have also negotiated separate independent-lab-type fee schedules with private insurers.

However, most hospital outreach labs bill commercial insurance plans for non-patient lab tests using their hospital chargemaster and related outpatient payer contracts to get payment rates that typically range from 1x to 5x times the current Medicare CLFS. In some cases, hospital outpatient lab rates to private insurers are as high as nine times the Medicare CLFS. In contrast, Quest Diagnostics, LabCorp and independent labs are paid at rates well below the Medicare CLFS.

A UHC spokesperson says that the policy applies to all UHC commercial plans, fully-insured and administrative-services only (ASO). It does not apply to UHC's Medicare or Medicaid plans.

UHC covers a total of 27.8 million commercial plan members in the United States, including 8.6 million fully-funded health plan members and 19.2 million ASO members in self-insured employer plans. Among the states where UHC has its biggest share of the commercial insurance market are Nevada (66% share), Texas (32%), Arizona (25%), Connecticut (26%), Florida (23%), North Carolina (22%), New York (16%) and Illinois (16%).

#### Why Is UnitedHealthcare Doing This?

Liff believes the UHC initiative is designed to force hospital labs off using outpatient fee schedules for non-patient testing to reduced, market-based, reference lab fee schedules. This will significantly lower payments to hospital labs for non-patient testing.

Liff notes that credentialing and contracting with UHC as a commercial lab provider is not expected to be a quick process and might take as long as 90-180 days, if not longer, for hospitals to complete.

It's important to note that hospital outreach labs do not have to change their licensure to an independent lab in order to continue providing non-patient lab services, but for reimbursement purposes the outreach lab will need to be recognized by UHC as a reference lab.

Liff adds that while it's unclear if UHC intends to exclude certain hospital outreach labs from receiving contracts under this new initiative, hospital lab leaders should be wary of this possibility.

#### Will Other Commercial Insurance Plans Follow Suit?

Other private payers will be closely observing the response to UHC's policy, says Jeff Myers, Vice President of Consulting at Accumen Inc. (Phoenix, AZ). He notes that private payers have been searching for effective ways to normalize payment rates made to hospitals, many of which have enjoyed premium payments from private payers for lab services for decades,

Myers adds that until Anthem's "rate alignment" strategy in 2019, efforts to lower hospital rates had been largely ineffective. But he believes that UHC's policy has the potential to have an even greater impact because it forces hospital labs to credential and contract with UHC as reference labs, or face denied claims for their non-patient lab testing.

Meanwhile, Myers anticipates that those hospitals that do credential and contract with UHC as a reference laboratory will likely see their non-patient lab payment rates decrease by 50% or more.

Hospitals that are already providing non-patient lab testing at competitive rates will have a distinct advantage over hospitals that have yet to make the market adjustment, adds Myers.

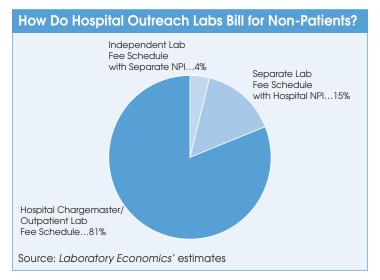


#### How Should Hospital Outreach Labs Respond To This New UHC Policy?

This a market shift that will require hospital leadership to make decisions about their ambulatory strategy going forward, including the consideration of adjusting prices to market levels to remain competitive. Some hospital leaders may consider selling their outreach lab business, while others may reinvest in their outreach program, viewing the UHC policy as an opportunity for growth, according to Myers.

#### How Many Hospital Outreach Labs Will Be Affected?

Using a cutoff point of \$50,000 per year in Medicare CLFS payments shows there are 2,527



hospital outreach labs doing business in the United States that bill under their hospital's NPI, according to Medicare OPPS claims data for 2018.

Laboratory Economics estimates that less than 15% of hospital outreach labs have separate independent reference lab fee schedules with commercial insurance companies like UHC. There are also approximately 100 hospital-owned labs with their own distinct NPI that bill separately from their hospital through independent reference lab fee schedules. But the overwhelming

majority of hospital outreach labs bill for non-patients using their hospital's outpatient lab fee schedule.

#### The Long-Term Consequences For Future PAMA Pricing Surveys

Efforts by the nation's two largest private health insurance companies (Anthem and UHC) to lower rates paid to hospital outreach labs will affect future Medicare CLFS rates. The current PAMA cycle covers private-payer lab rates collected in the first half of 2019, which will be reported to CMS in the first three months of 2021, and used to set Medicare CLFS rates for 2022-2024. The new Anthem and UHC policies designed to lower hospital outreach lab rates will impact PAMA pricing surveys and Medicare CLFS rates thereafter.

 $For more information, see United Healthcare \ Network \ Bulletin \ February \ 2020, \ Page \ 16 \ (https://www.uhcprovider.com/content/dam/provider/docs/public/resources/news/2020/network-bulletin/february-2020-network-bulletin.pdf)$ 

# Why Were Hospital Labs Excluded From The Initial PAMA Survey?

Aformer CMS official involved in drafting the initial Medicare rules that determined which labs must report their private-payer pricing data to CMS for calculating Medicare CLFS rates says that PAMA was specifically designed to exclude hospital labs. This flies in the face of the lab industry's contention that the PAMA law intended pricing information from all labs, including hospital labs, to be included in the rate calculations.

Speaking at the Annual Meeting for the American Clinical Laboratory Assn. (ACLA), March 4, Marc Hartstein, a Principal with Health Policy Alternatives and former Director of CMS's Hospital and Ambulatory Policy Group, said, "I provided technical assistance to the Senate Finance Committee, which wrote the statute, and I can tell you the intent was to exclude hospital laboratories. The provision was intended to get savings, and if hospital laboratories were included, that would have raised the payment amounts."

Hartstein spent 26 years at CMS (1990-2016) and helped develop such major Medicare policies as the misvalued code initiative for the physician fee schedule, the hospital Diagnosis-Related Group system, the hospital two-midnight rule, as well as the regulations for implementing Medicare's new CLFS under PAMA.

At this point, the opinions of those involved in drafting the PAMA statute don't really matter, said Hartstein, who noted that it's now up to the court to issue a statutory interpretation of the law. "Courts rightly decide issues based on the words of the law, not the opinions of those involved in drafting or enacting the law," he said. ACLA's lawsuit challenging the implementation of PAMA (originally filed in December 2017) is now awaiting a ruling from Judge Amy Berman Jackson from the U.S. District Court for the District of Columbia. Judge Jackson initially dismissed the case, but ACLA won an appeal, and the case was sent back to her to make a ruling. All briefs and replies were submitted to Judge Jackson at the end of January, and a decision is expected by year's end.

"The question is whether the secretary's definition of 'laboratory' is a reasonable definition," said Hartstein. "If a laboratory is only a laboratory and not its larger organization, the laboratory is going to get 100% of its [Medicare] revenues from the clinical laboratory fee schedule or physician fee schedule. I don't understand what the majority revenues criterion would be in that circumstance. The majority of revenue criterion must have been drafted to eliminate somebody from this determination."

Regardless, the second PAMA reporting cycle now requires hospital labs to report their private-payer data for non-patients to CMS in the first quarter of 2021. The hospital data, along with data from independent labs and POLs, will be used to calculate Medicare CLFS rates for 2022-2024.

Finally, the Medical Payment Advisory Commission (MedPAC) is currently reviewing how CMS has implemented the private-payer-based CLFS under PAMA, giving the lab industry an opportunity to make its case for a different system, said Hartstein. The lab industry wants CMS to analyze the payment data it collects from labs using statistical sampling to ensure that all sectors of the lab market are accurately represented.

# **Exact Sciences Buys Paradigm Diagnostics**

Exact Sciences has acquired Paradigm Diagnostics (Phoenix, AZ) in a stock transaction for an undisclosed amount. Paradigm, which has 31 employees, operates a CAP-accredited lab in Phoenix that specializes in genomic profiling.

The company's lead product is Paradigm Cancer Diagnostic (PCDx), a tumor tissue sequencing test that guides treatment for lung, breast and colon cancer patients. PCDx analyzes 234 genes to match cancer patients with the best treatment option from 90+ available drugs (both FDA approved and investigational). Results are provided within 3-5 days of sample pickup.

PCDx has a list price of \$4,800. Most of the company's customers are oncologists, but it also sells to academic medical centers. Palmetto GBA, a Medicare Administrative Contractor that assesses molecular diagnostic technologies under its MolDx program, recently covered PCDx under its existing local coverage determination for next-gen sequencing for solid tumors. Exact plans to introduce a blood-based version of PCDx.

Paradigm has estimated annual revenue of more than \$10 million. The company was co-founded by its Chief Executive David Mallery and Chief Scientific Officer Scott Morris, PhD, in 2012. Paradigm had raised more than \$15 million from a group of private equity firms led by Mesa Verde Venture Partners and New Science Ventures.

# Spotlight Interview With InCyte Diagnostics CEO Patty Sipes

InCyte Diagnostics (Spokane Valley, WA) has focused on pathology in the past but is now ready to move into clinical laboratory testing. The lab, which is pathologist-owned and has 350 employees, including 50 pathologists, will open its new facility at the end of March. *Laboratory Economics* recently spoke with Chief Executive Patty Sipes.



Patty Sipes

#### Can you give us a brief overview of InCyte Diagnostics?

We specialize in pathology, including a wide array of subspecialties such as hematopathology, dermatopathology, gastropathology, neuropathology and oral pathology. Our geographic market is primarily the Pacific Northwest – Washington, Idaho, Oregon, Montana and Alaska.

We have approximately 1,000 physician practice and clinic clients and 50 hospital contracts. In 2019, we had 233,000 surgical cases, and performed 125,000 pap smears, 16,000 non-gyn, 2,300 flow cytometry and 205,000 molecular tests.

Our reference labs for AP services are Neogenomics and Hematologics. For the new clinical lab, it's going to be Mayo.

#### Are you growing in terms of volumes and revenues? If yes, by how much?

Definitely. Our overall growth rate is 7% to 9%, which is above the industry average. Our February data is showing biopsies alone are up 12% and women's health is up 19%. We have brought in a lot of new clients. We've seen a decrease in overall cytology because of changes in guidelines for Pap smears, but we have increased our test menu in molecular and FISH.

#### Do you have any plans to expand into other areas?

Our biggest opportunity has been the development of a clinical laboratory. We started the project last spring, and we will go live at the end of this month. We remodeled 13,000 feet of a building that is located 1.5 miles away from our main lab.

Our menu will have several hundred tests to accommodate anything coming from an OB/GYN office, pediatricians, internal med or general practitioner. About 90% of testing will be done in house. Whatever we send out will go to Mayo.

We are expecting a lot of business in the new lab – several million dollars. All our projections were done factoring in the PAMA cuts. Our biggest competitors will be LabCorp and Quest Diagnostics. People like the fact that we are local; we have excellent turnaround times and we are willing to communicate with them.

#### Do you use digital pathology?

We do, we use it for both primary and secondary diagnoses. Primary is used for GI cases, IHC and special stains, everything else is secondary. Primary is good for cases that are not as complex.

#### Are you testing for Covid-19?

Not yet, but we have implemented a task force to look into it.

#### What has your experience been with the PAMA Medicare CLFS cuts?

We have not found it to be overly negative. We have been creative in our contract negotiations with private payers.



#### Have you had any problems with data submission?

We submitted PAMA data for the initial reporting cycle. We expect to have several challenges in the collection of the data for the next reporting period in first quarter 2021.

#### What do you see as your biggest challenge?

Finding ways to keep our employees. We have a multi-generational workforce who are futureoriented and want to connect their work and its impact. We have created an employee retention committee so they can bring about positive change in our organization. They recommended some changes to benefits, such as increased health coverage for dependents and more transparency, many of which we implemented. We need to really think differently about how we can keep employees longer.

In terms of hiring, it's been challenging finding qualified candidates in histology. We have an arrangement with the University of North Dakota where we put students through their histotech training program, so that helps.

#### Harbert Wins Two Board Seats At Enzo Biochem

wo nominees from the Alabama investment management firm Harbert Discovery Fund (HDF) have won board seats at Enzo Biochem (New York City), following a vote at Enzo's delayed shareholders meeting on February 25. Fabian Blank and Peter Clemens now represent 40% of the voting power on Enzo's five-person board. Shareholders rejected Enzo's proposal to amend the company's bylaws to increase the size of the Board (see *LE*, February 2020).

The board seat of Elazar Rabbani, PhD, Co-Founder, Chairman and CEO of Enzo Biochem, is set to expire at the next shareholders meeting in early 2021.

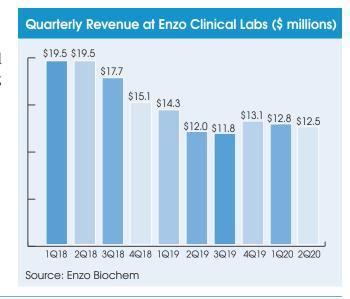
HDF owns 11.8% of Enzo's outstanding shares, making it the company's largest shareholder. HDF has been pressuring Enzo to sell its drug development business and focus on its clinical lab business.

Separately, Enzo reported a net loss of \$7.7 million for the three months ended January 31, 2020, compared with a net loss of \$8.4 million for the same period a year earlier. Total revenue was up slightly to \$19.4 million versus \$19.3 million.

Enzo reported that its clinical lab division recorded revenue of \$12.5 million for the quarter, up 4% from \$12 million. Patient requisition volume was up 7%, while average revenue per requisition

was down approximately 3%. Gross profit margin for Enzo's clinical lab division was 18% in the most recent quarter versus 8% in the same year-ago period. Enzo attributed the margin expansion to cost cuts, including lowered outside reference testing expense and employee headcount efficiencies, partially offset by increased reagent cost from higher accession volume. On an annual basis, Enzo currently processes approximately 813,000 patient requisitions.

Enzo's latest results suggest that the company's clinical lab business has begun to stabilize after several years of severe pricing pressure related to the PAMA reimbursement cuts.



# Publicly-Traded Labs Grew By 4.2% In 2019

On a combined basis, 17 publicly-traded labs grew their revenue by 4.2% to \$20.2 billion in 2019 (after adjusting for acquisitions), according to financial reports collected by *Laboratory Economics*.

Revenue growth at the big routine clinical lab companies (Quest, LabCorp, Sonic, BioReference and Enzo) grew by a weighted average of 0.2% last year (after adjusting for acquisitions) to a combined total of \$16.5 billion.

Revenue growth was much faster at 11 molecular/genetic-testing lab companies, which grew by a weighted average of 29.9% in 2019 (after adjusting for acquisitions) to a combined total of \$3.6 billion.

The fastest revenue growth occurred at Guardant Health (up 136.5%), which markets liquid biopsy test panels; Castle Biosciences (up 127.6%), which markets a gene expression profile test for melanoma; and Exact Sciences (up 78%), which sells a stool-based DNA test for colorectal cancer screening.

#### Revenue Growth at 17 Publicly-Traded Lab Companies (\$000)

Company	Revenue 2019	Revenue 2018	Reported Change	Pro Forma Change*
Quest Diagnostics	\$7,726,000	\$7,531,000	2.6%	1.0%
LabCorp Diagnostics	7,000,100	7,030,700	-0.4%	0.4%
Sonic Healthcare USA (1)	1,008,700	858,468	17.5%	5.0%
Exact Sciences	876,293	454,462	92.8%	78.0%
Myriad Genetics (2)	851,100	743,700	14.4%	-4.0%
Opko/BioReference Labs	716,434	813,248	-11.9%	-11.9%
Genomic Health (3)	456,364	394,111	15.8%	15.8%
NeoGenomics	408,830	276,741	47.7%	11.1%
Natera Inc.	302,328	257,654	17.3%	17.3%
Invitae Corp.	216,824	147,699	46.8%	46.8%
Guardant Health	214,375	90,639	136.5%	136.5%
CareDx	127,068	76,569	66.0%	66.0%
Veracyte	120,368	92,008	30.8%	30.8%
Castle Biosciences	51,865	22,786	127.6%	127.6%
Enzo Clinical Labs (4)	51,115	71,077	-28.1%	-28.1%
Psychemedics	37,678	42,674	-11.7%	-11.7%
DermTech	3,364	2,442	37.8%	37.8%
Total, 17 companies	\$20,168,806	\$18,905,978	6.7%	4.2%
5 Routine Labs	\$16,502,349	\$16,304,493	1.2%	0.2%
11 Molecular/Genetic Labs	\$3,628,779	\$2,558,811	41.8%	29.9%

<sup>\*</sup>Pro forma change is estimated by Laboratory Economics after adjustments for acquisitions.

Source: Laboratory Economics from company reports

<sup>&</sup>lt;sup>1</sup>Sonic Healthcare USA's revenue is for fiscal year ended June 30, 2019 (using constant exchange rate of 1 AUD = 0.70 USD; <sup>2</sup>Myriad Genetics' revenue is for fiscal year ended June 30, 2019; <sup>3</sup>Genomic Health was acquired by Exact Sciences on November 8, 2019; <sup>4</sup>Enzo's revenue is for lab services only for fiscal year ended July 30, 2019.



# Comparing Productivity At Quest, LabCorp And BioReference For 2019

On a weighted basis, three publicly-traded lab companies collected average revenue of \$44.85 per requisition in 2019. Average collected revenue per test was an estimated \$13.59.

The three companies—Quest Diagnostics, LabCorp and OPKO's BioReference Labs—generated a weighted average of \$170,636 in revenue per employee in 2019. The average number of requisitions processed was 3,804 per employee, while employees processed an average of 12,555 tests. These figures are based on the total number of employees at the three companies, including all administrative, couriers, sales and marketing, and lab technical staff.

In terms of billing and collection, the average bad-debt expense for the big three commercial labs is approximately 4.5% with an average days in accounts receivables of 45 days. The combined revenue mix at the three publicly-traded labs is approximately 41% from private healthcare insurance, 30% client bill, 11% Medicare CLFS, 1% from Medicare PFS, 2% Medicaid and 13% paid directly from patients (including copays and deductibles).

#### Productivity Stats at Quest, LabCorp and BioReference for 2019

	Quest	LabCorp	BioReference	
2019 Financials	Diagnostics	Diagnostics*	Laboratories	Total
Annual Revenue 2019	\$7,726,000,000	\$7,000,100,000	\$716,434,000	\$15,442,534,000
Operating Income 2019	\$1,231,000,000	\$1,086,000,000	-\$123,359,000	\$2,193,641,000
# Employees	47,000	39,000	4,500	90,500
Employee Efficiency				
Avg. Annual Revenue per Employee	\$164,383	\$179,490	\$159,208	\$170,636
Avg. Annual Operating Income per Employee	\$26,191	\$27,846	-\$27,413	\$24,239
Requisition Stats				
Est'd Annual Requisitions 2019	175,000,000	158,400,000	10,900,000	344,300,000
Est'd Avg. Revenue per Requisition	\$43.86	\$44.20	65.73	\$44.85
Est'd Avg. Operating Income per Requisition	\$7.03	\$6.86	-\$11.32	\$6.37
Est'd Avg. Reqs processed per Employee	3,723	4,062	2,422	3,804
Test Stats (~3.3 tests per req.)**				
Est'd Annual Test Volume 2019**	577,500,000	522,720,000	35,970,000	1,136,190,000
Est'd Avg. Revenue per Test	\$13.29	\$13.39	\$19.92	\$13.59
Est'd Avg. Operating Income per Test	\$2.13	\$2.08	-\$3.43	\$1.93
Est'd Avg. Tests processed per Employee	12,287	13,403	7,993	12,555
Billing Stats				
Est'd Bad-Debt % (pre-ASC 606)	4% - 4.5%	4% - 4.5%	5% - 10%	4.5%
Days in AR	40-50	40-50	50-75	45
Revenue by Payer				
Healthcare Insurers	36.0%	44.0%	58.5%	40.7%
Client Payers (physicians, hospitals, et al.)	32.0%	28.3%	22.3%	29.9%
Private Patients	13.0%	13.2%	2.9%	12.6%
Medicare CLFS	11.0%	11.7%	11.0%	11.3%
Medicare PFS	1.0%	0.6%	1.7%	0.9%
Medicaid	3.0%	2.2%	2.0%	2.6%
Other	4.0%	0.0%	1.6%	2.1%

<sup>\*</sup>Data is for LabCorp's lab testing business only. \*\*Test volume stats assume an average of 3.3 tests per requisition.

Source: Company reports and Laboratory Economics' estimates

# The Consequences From Pandemic Precautions Will Be Significant

The unfortunate truth is that millions of Americans are likely to test positive for the Covid-19 virus and thousands may die from it. Only time will tell.

But has the response from politicians, public health officials, cable news and the popular press been appropriate relative to the actual misery that will be caused by Covid-19? It seems the only acceptable reaction is to advise and implement policies that exercise an overabundance of safety and caution.

However, off-the-record conversations and emails with half-a-dozen doctors, physician assistants and nurses who are actually working in hospitals and clinics in New York City suggest that the nation might be overreacting to Covid-19.

The director of infectious disease at a big hospital said, "This is 99% fear. The people who should take extra precautions are those with underlying health issues (asthma, smokers, lung or heart conditions). Otherwise people need to maintain proper hygiene."

An emergency room nurse with 30+ years of experience describes the apparent overreaction as like being in an episode of The Twilight Zone.

"This is not the zombie apocalypse," said a physician assistant. "If you are feeling mildly ill, consider just staying home as a courtesy to your fellow humans."

Maybe the frontline healthcare workers that *Laboratory Economics* contacted have become callous and indifferent after decades of living and working in New York City. But regardless of whether you think that the response to Covid-19 has been too much or too little, there will be serious repercussions as result of travel bans and worker quarantines.

#### Potential Medical Supply Shortages and Delays

A number of factors have increased the risk of shortages of medical supplies, and current deliveries for some items are taking longer than normal. Many governments, including the United States, are now restricting travel into their countries.

This raises several concerns. The first is that many medical supplies are delivered by air to the U.S. via European hubs. But the U.S. has now placed restrictions on passengers coming from Europe. A significant portion of medical supplies travel in the cargo areas on passenger planes. Without passengers to fly on those planes, the cargo that would otherwise travel on passenger planes might also not travel or become prohibitively costly to transport. Flight cancellations and re-routing may cause delays in delivery of medical supplies, including drugs, test reagents, masks, gloves, sample collection swabs, et al.

Secondly, global supply chains in numerous industries are being affected. When it comes to pharmaceuticals and certain test reagents, many of the ingredients and components used to produce finished products are manufactured in China, where the coronavirus has had the greatest impact on factory production to date. Further complicating things is that some countries have begun to ban the export of at least some medical supplies and drugs in an effort to preserve supplies for their local populations.

#### Amplifying the Laboratory Worker Shortage

The laboratory work force was already stretched thin prior to Covid-19, especially for couriers, phlebotomists, lab technicians and medical technologists. Two-week self-quarantines for anyone suspected of having Covid-19 will be particularly hamstringing to labs whose workers don't have the option of working from home.

### Lab Stocks Down 11% Year To Date

Twenty lab stocks have fallen by an unweighted average of 11% year to date through March 13. In comparison, the S&P 500 Index is down 16% so far this year. The top-performing lab stocks thus far in 2020 are Interpace Biosciences, up 30%, and Opko Health, up 29%. Shares of LabCorp are down 11%, while Quest Diagnostics is down 9%.

Company (ticker)	Stock Price 3/13/20	Stock Price 12/31/19	2020 Price Change	Enterprise Value (\$ millions)	Annual Revenue (\$ millions)	Enterp Value/ Annual Revenue
LabCorp (LH)	\$151.02	\$169.17	-11%	\$24,970	\$11,555	2.2
Quest Diagnostics (DGX)	96.77	106.79	-9%	19,660	7,726	2.5
Sonic Healthcare (SHL.AX)	29.01	28.75	1%	17,590	6,570	2.7
Exact Sciences (EXAS)	55.22	92.48	-40%	10,950	876	12.5
Guardant Health (GH)	70.74	78.14	-9%	7,380	214	34.4
NeoGenomics (NEO)	25.64	29.25	-12%	3,160	409	7.7
Natera (NTRA)	30.80	33.69	-9%	2,800	302	9.3
Invitae (NVTA)	12.23	16.13	-24%	1,910	217	8.8
Myriad Genetics (MYGN)	13.30	27.23	-51%	1,280	813	1.6
Opko Health (OPK)	1.90	1.47	29%	1,250	901	1.4
Veracyte (VCYT)	21.16	27.92	-24%	1,090	120	9.1
CareDx (CDNA)	19.95	21.57	-8%	963	127	7.6
Castle Biosciences (CSTL)	24.07	34.37	-30%	429	52	8.3
Exagen (XGN)	18.70	25.40	-26%	208	40	5.2
DermTech Inc. (DMTK)	13.08	12.40	5%	205	3	61.1
Enzo Biochem (ENZ)	2.61	2.63	-1%	160	80	2.0
Vermillion Inc. (VRML)	0.74	0.81	-9%	79	4	19.1
Psychemedics (PMD)	6.50	9.15	-29%	45	38	1.2
Interpace Biosciences (IDXG)	6.48	5.00	30%	36	26	1.4
Biocept (BIOC)	0.30	0.29	3%	9	5	1.9
Unweighted Averages			-11%	\$94,173	\$30,079	3.1

Source: Laboratory Economics and Capital IQ

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