

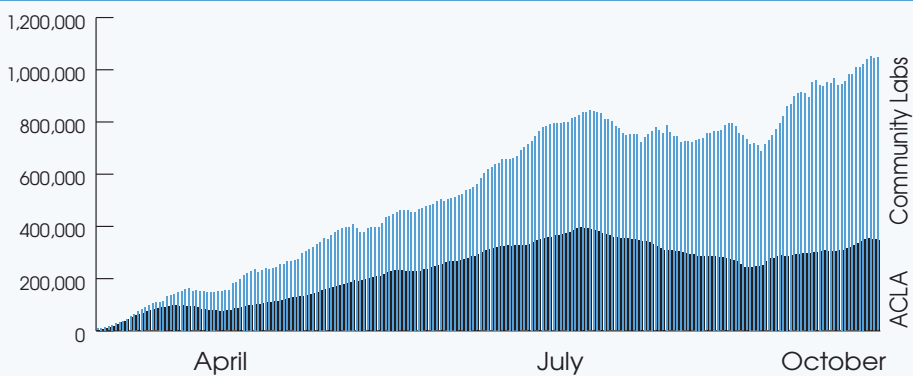
LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

Covid-19 PCR Tests Reach 1 Million Per Day

With a new flu season just starting, the volume of Covid-19 PCR testing performed in the United States is currently averaging more than 1 million tests per day, according to the Covid Tracking Project. This exceeds the previous peak in testing that occurred in late July at the height of outbreaks in the Southeast and Sun Belt states. Meanwhile, Covid-19 PCR testing seems to be shifting more to local hospitals and independent labs. ACLA member labs' share of Covid-19 PCR testing has fallen to 33% in mid-October from 50% in mid-July. For more on Covid-19 testing and *LE's* latest survey results, see pages 8-9.

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



*Seven-day moving average

Source: The Covid Testing Project and ACLA

Genetic Tests Continued To Dominate Medicare Spending Growth In 2019

Genetic tests accounted for 18 of the top 25 fastest-growing clinical lab and pathology tests in 2019, according to an *LE* analysis of newly released data on Medicare Part B Carrier payments from CMS. Overall, Medicare payments for genetic tests were up 46% to \$1.647 billion in 2019. Over the three-year period from 2016 to 2019, Medicare payments for genetic tests increased by an average of 51% per year. In comparison, routine clinical lab test payments fell by 7% in 2019 and decreased by an average of 2% per year from 2016 to 2019. *Full details on pages 2-3.*

Medicare Part B Carrier Spending on Lab & Pathology Tests

Category	2019	1-Year Change	3-Year CAGR
Genetic Testing	\$1,647,079,631	46%	51%
Anatomic Pathology	\$1,616,182,495	2%	0%
Drug Testing	\$886,944,077	-3%	8%
Routine Clinical	\$3,649,014,636	-7%	-2%
Pap & HPV Testing	\$57,915,782	-9%	-7%
Grand Total	\$7,857,136,621	3%	5%

Source: *Laboratory Economics* from Medicare Part B National Summary Data Files

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Genetic Tests Dominated Medicare Spending Growth (cont'd from page 1)

The data analyzed covers Medicare CLFS and PFS payments made to labs and physicians, but not payments made to hospitals through fiscal intermediaries.

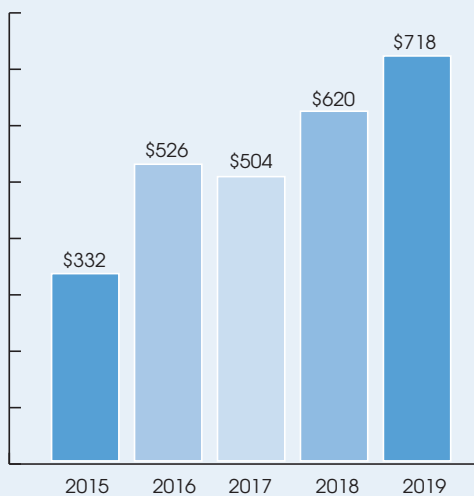
The fastest-growing tests in 2019 were CPT 81407 (Molecular Pathology Procedure, Level 8), up 200%; 0037U (FoundationOne CDx), up 139%; and 81162 (BRCA 1&2 Gene Analysis), up 138%.

In addition to Roche's FoundationOne CDx test, there were three other proprietary genetic tests on the top 25 list, including Exact Sciences' ColoGuard, up 44%; Veracyte's Afirma Gene Expression Classifier, up 14%; and Agendia's MammaPrint, up 11%.

DNA-based infectious disease testing was the other fast-growing category with six tests among the top 25. The fastest-growing test in this category was CPT 87801 (Infectious Agent Detection by Nucleic Acid; Multiple Organisms), up 120%.

The sole anatomic pathology test in the top 25 was CPT 88350 (Immunofluorescence, per Specimen; each Additional Single Antibody Stain Procedure), up 13%.

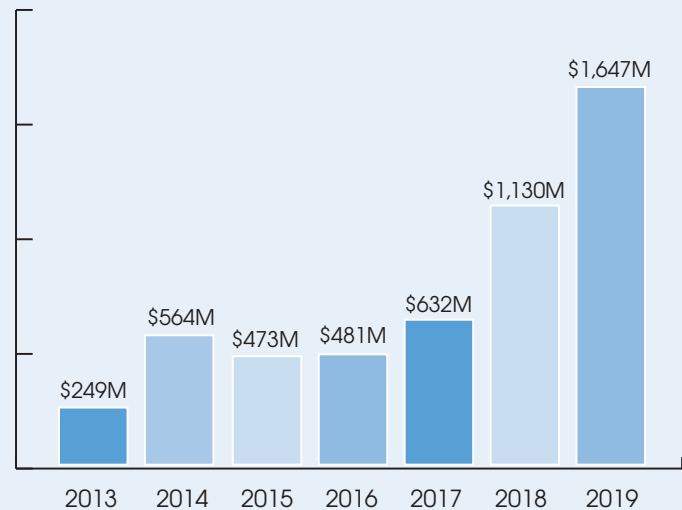
Average Allowed Medicare Charge Per Genetic Test*



*Weighted average for all Molecular Pathology Tests, Multianalyte Algorithmic Assays, Genomic Sequencing Procedures, Proprietary Laboratory Analyses codes and G0452 (molecular pathology interpretation)

Source: *Laboratory Economics* from Medicare Part B National Summary Data Files, 2015-2019

Medicare Part B Carrier Spending on Genetic Tests*



*Total Medicare Part B Carrier payments for all Molecular Pathology Tests, Multianalyte Algorithmic Assays, Genomic Sequencing Procedures, Proprietary Laboratory Analyses codes and G0452 (molecular pathology interpretation)

Source: *Laboratory Economics* from Medicare Part B National Summary Data Files, 2013-2019

Overall, Medicare Part B Carrier spending on lab and pathology tests increased by 3% to \$7.857 billion in 2019. As mentioned earlier, the fastest-growing category was genetic testing, up 46% to \$1.647 billion. This followed a 79% jump in 2018 (see *LE*, August 2020). These spikes were caused by a significant increase in utilization of unnecessary genetic cancer tests in 2018 and 2019, according to the 2020 Medicare Trustees Report. This allegedly fraudulent utilization was stopped in late 2019 and spending on genetic tests is expected to slow in 2020 and beyond, according to the report.

Meanwhile, Medicare Part B Carrier spending on routine clinical lab tests fell by 7% in 2019 because of the PAMA rate cuts. The average allowed charge for a routine clinical lab test was \$13 in 2019 versus an average of \$718 for genetic tests.

Fastest-Growing Lab & Pathology Tests by Medicare Payments for 2019

CPT	Short Description	2019 Payment	2018 Payment*	1-Year % Chg
81407	Molecular Pathology Procedure, Level 8	\$17,739,535	\$5,906,375	200%
0037U	Targeted Genomic Sequence Analysis (FoundationOne CDx)	78,338,284	32,728,869	139%
81162	BRCA 1&2 Gene Analysis	118,521,577	49,860,043	138%
81408	Molecular Pathology Procedure, Level 9	283,982,476	120,688,407	135%
81599	Unlisted Multianalyte Assay with Algorithmic Analysis	28,088,766	12,309,679	128%
87801	Infectious Agent Detection by Nucleic Acid (DNA or RNA); Multiple Organisms	20,763,398	9,427,984	120%
87481	Infectious Agent Detection by Nucleic Acid (DNA or RNA); Candida	16,472,786	7,873,818	109%
87798	Infectious Agent Detection by Nucleic Acid (DNA or RNA); Not Otherwise Specified	98,683,358	49,150,431	101%
81406	Molecular Pathology Procedure, Level 7	42,214,830	21,850,413	93%
81317	PMS2 Gene Analysis	53,573,782	31,588,686	70%
81298	MSH6 Gene Analysis	42,449,143	26,307,256	61%
81201	APC Gene Analysis	47,249,802	29,785,160	59%
81295	MSH2 Gene Analysis	25,205,062	15,900,312	59%
81479	Unlisted Molecular Pathology Procedure	197,406,615	132,638,865	49%
81528	Genetic Test Analysis, Colorectal Cancer (Cologuard)	240,682,190	167,191,703	44%
81321	PTEN Gene Analysis	10,747,241	7,638,677	41%
87799	Infectious Agent Detection by Nucleic Acid (DNA or RNA); Not Otherwise Specified; Quantification	14,308,447	11,281,832	27%
81405	Molecular Pathology Procedure, Level 6	10,965,971	8,747,436	25%
81292	MLH1 Gene Analysis	10,203,749	8,280,887	23%
87661	Infectious Agent Detection by Nucleic Acid (DNA or RNA); Trichomonas Vaginalis	6,866,958	5,649,910	22%
87502	Infectious Agent Detection by Nucleic Acid (DNA or RNA); Influenza Virus	10,098,055	8,323,937	21%
81404	Molecular Pathology Procedure, Level 5	12,755,555	10,844,908	18%
81545	Thyroid Gene Expression Analysis (Afirma Gene Expression Classifier)	25,357,454	22,337,668	14%
88350	Immunofluorescence, Per Specimen; each Additional Single Antibody Stain Procedure	10,180,708	8,981,309	13%
81521	Breast Cancer Microarray Gene Expression (MammaPrint)	11,750,771	10,581,631	11%
	Total, Top 25 Tests	\$1,434,606,513	\$815,876,195	76%
	Genetic Testing**	1,647,079,631	1,129,787,494	46%
	Anatomic Pathology	1,616,182,495	1,588,353,052	2%
	Drug Testing	886,944,077	914,863,739	-3%
	Routine Clinical Lab Tests	3,649,014,636	3,911,136,287	-7%
	Pap & HPV Testing	57,915,782	63,455,538	-9%
	Grand Total, All Medicare Part B Carrier Test Payments	\$7,857,136,621	\$7,607,596,110	3%

*Test codes must have had a minimum of \$5 million in Medicare Part B Carrier spending in 2018 to be included in list.

**Includes all Molecular Pathology Tests, Multianalyte Algorithmic Assays, Genomic Sequencing Procedures, Proprietary Laboratory Analyses codes and G0452 (molecular pathology interpretation).

Source: *Laboratory Economics* from Medicare Part B National Summary Data Files, 2018 & 2019

Spotlight Interview With Quest Diagnostics' Jay Wohlgemuth

Year to date, Quest Diagnostics has performed more than 15.7 million Covid-19 PCR tests in the United States as well as 3.8 million antibody tests. *Laboratory Economics* recently spoke with Jay Wohlgemuth, MD, Senior Vice President and Chief Medical Officer at Quest Diagnostics, for insight into the company's Covid-19 testing strategy.



Jay Wohlgemuth,
MD

Approximately how many Covid-19 PCR tests is Quest Diagnostics currently performing?

We're performing between 100,000 and 130,000 Covid-19 PCR tests per day and volumes have started to edge up as we enter the fall. Our current capacity is 200,000 tests per day. Testing is performed at 20 labs around the country with the highest volumes at San Juan Capistrano, California and Chantilly, Virginia. Our primary test systems are Thermo Fisher's AVI, Roche and Hologic.

Are you experiencing any supply or employee shortages?

It's tough finding field-based employees who have been trained to make onsite nasal swab collections. Quest and its ExamOne subsidiary are performing testing for large employers, universities and sports teams throughout the country. Before doing the nasal swab collection, phlebotomists and other healthcare technicians are required to have one week of training. Finding these trained workers and temporarily relocating them to different collection sites throughout the country for a week at a time can be a challenge.

Can you describe how Quest Diagnostics is using pooled testing for Covid-19?

We started PCR testing of pools with four patient specimens at a time in July. We're using it in areas where the positivity rate is less than 5%. Roughly 25% of our daily Covid-19 PCR tests currently come from pooled testing. It's helped us expand our capacity.

The U.S. national positivity rate for Covid-19 PCR tests is currently hovering around 5%. What do the other 95% of people that test negative typically have?

There's quite a bit of asymptomatic testing going on, so many people have nothing. For those with symptoms, they are most likely affected with a benign coronavirus or a common flu. But as we enter the flu season, the chances of having something more serious, like influenza A or B, or respiratory syncytial virus (RSV), will rise.

There's been very little activity so far this flu season, but I expect to see a pickup later this month and into November. The symptoms of Covid-19, influenza A/B and RSV are very similar, so utilization of new combination tests of Covid-19 and influenza A/B and respiratory viral panels that include Covid-19 will increase in the coming weeks. These combination tests should also help minimize the use of specimen collection materials amid continuing supply constraints.

What steps has Quest taken to reduce turnaround times for Covid-19 PCR test results?

We saw a surge in demand over the summer that resulted in a backlog. Over the past few months, we've eliminated the backlog and now have turnaround times—from time of specimen pickup to result reporting—of 1-2 days for priority patients (hospital patients, nursing home residents and presurgical patients) and within two days for all others.

Among the steps taken were 1) increasing capacity to 200,000 tests per day, in part through pooled testing; 2) enhancing systems to identify and process priority 1-3 patient specimens; 3) more quickly identifying potential bottlenecks so specimens can be routed to Quest network labs with spare capacity; and 4) turning down test orders when demand exceeds capacity. In addition, some of the demand pressure has been alleviated as other labs have increased their capacity.

Do you expect demand for Covid-19 antibody testing to pick up?

Currently, Quest is performing about 15,000 Covid-19 serology tests per day and has the ca-

capacity for up to 200,000 per day. We're using highly specific IgG antibody tests from Abbott and Ortho Clinical Diagnostics.

When vaccines start coming on the market, I expect there will be high interest in the associated antibodies. Antibody testing will be used to confirm that those vaccinated, especially immunocompromised individuals, were infected, developed antibodies, recovered, and are now extremely unlikely to get ill again or infect others.

In addition, Quest is planning to soon introduce new quantitative antibody tests for Covid-19. Quantitative antibody testing has the potential utility of demonstrating whether or not someone who has been infected with SARS CoV-2 has protective levels of IgG antibodies. This testing can also be useful for identifying individuals who may be effective convalescent plasma donors or as a measure of vaccine efficacy.

What have you learned from antibody testing so far?

That the virus is much more widespread than PCR testing alone has revealed.

Quest is among the commercial labs that has partnered with the CDC to conduct ongoing national seroprevalence surveys to estimate the percentage of people who were previously infected with Covid-19. Since July, we've been sending the CDC blood samples from patients tested for reasons unrelated to Covid-19, such as for lipid tests or liver tests, so they can run antibody tests on an unbiased sample set. Initial results covering the first two weeks of August showed estimated prevalence nationwide was 10-fold higher than the number of cases reported from PCR testing alone.

In some high-population-density areas of the country, such as New York City and northern New Jersey, seroprevalence rates are as high as 40%.

Can you describe the study that Quest scientists recently published concerning Vitamin D?

Scientists from Quest Diagnostics and Boston University School of Medicine published a study in PLoS ONE (Sept. 17, 2020) that found that Covid-19 PCR test positivity is strongly and inversely associated with vitamin D blood levels, a relationship that persists across geographies, races/ethnicities, sexes, and age ranges. With emerging information on Vitamin D and its role in Covid-19, doctors have expressed interest in ensuring their patients have appropriate levels of Vitamin D as determined by guidelines.

What's the biggest misconception that the mass media and general public have about Covid-19?

The public and media understand that testing is a critical component of our pandemic response. However, there is a lack of understanding on the variability in quality and accuracy of the many available tests (not all PCR and antigen tests are equal). Also, even highly accurate testing needs to be interpreted in the context of the complete clinical picture when trying to determine an individual's disease status and likely level of infectiousness.

What's happening with non-Covid-19 testing volumes?

We are seeing a return to normal levels of testing for many chronic diseases like diabetes and high cholesterol. The biggest concern is getting "caught up" with all the cancer screening and diagnostic workups which did not happen when they needed to over the year. This is clearly leading to diagnosis of cancers at later stages and we need to get back to a place where these cancer screenings and testing workups are no longer delayed and happening when they need to. In addition, drug monitoring has not returned to prior testing levels despite signs that drug abuse—both illegal and diversion of prescription drugs—is surging.

How do you envision the Covid-19 pandemic ending?

I expect an FDA approved vaccine(s) to be effective, and once widely distributed to a large percentage of the population, this pandemic will be over. Then the question will be "Have we properly prepared ourselves for any potential new pandemics that occur in the future?"

CorePlus Details Its Use Of Artificial Intelligence For Prostate Cancer

Last month, *LE* briefly noted that CorePlus Servicios Clínicos y Patológicos LLC (Carolina, Puerto Rico) had become the first independent lab in the Americas to begin using artificial-intelligence-assisted (AI) pathology for prostate cancer diagnostics. This month we got in touch with CorePlus President Mariano de Socarraz to find out more.



Mariano de
Socarraz

Can you describe CorePlus?

We opened our CLIA-certified laboratory in Carolina, Puerto Rico in 2008. We currently have 115 employees, including four pathologists. CorePlus is full-service independent laboratory. Among our specializations is uropathology. We process approximately 3,000 prostate cancer cases (~36,000 slides) per year, representing more than half of all outpatient prostate cancer biopsies performed in Puerto Rico.

Is operating a lab in Puerto Rico different than in mainland United States?

No. Puerto Rico is a U.S. territory that must follow all federal lab regulations, including CLIA. Medicare and Medicaid insurance cover the majority of the 3.2 million people living in Puerto Rico and the biggest private insurer is Triple-S, which is an independent licensee of the Blue Cross Blue Shield Association. The biggest difference is probably reimbursement rates, which are substantially lower in Puerto Rico.

Among the competing clinical labs in Puerto Rico are Laboratorio Clinico Toledo and Laboratorios Borinquen. Anatomic pathology labs include Hato Rey Pathology and Puerto Rico Pathology. Quest Diagnostics has had a reduced presence following the damage to its lab facilities from Hurricane Maria in 2017. LabCorp transports specimens to its labs in Florida.

When did CorePlus transition to digital pathology?

We began digitizing slides using 3DHISTECH scanners in mid-2019. By late 2019 we had completed validation and by early 2020 our pathologists were reading digitized images for all our pathology cases, including all routine histopathology and stains.

What type of computer screens do your pathologists read the digital slide images from?

CorePlus validated the Dell UltraSharp 49 Curved Monitor - U4919DW. It's a high-end, business grade monitor with a Delta E of <2 (color difference perception) and an aspect ratio of 32:9:0. This aspect ratio is the equivalent of two 27-inch monitors running at 2K.

And how did you get involved with AI-assisted pathology?

In August 2018, I read about a validation study conducted by University of Pittsburgh Medical Center which used an AI-based algorithm to detect and characterize prostate cancer from digitized slides. This study [recently published in *The Lancet Digital Health*] showed that an AI-based algorithm demonstrated 98% sensitivity and 97% specificity at detecting prostate cancer from 1,600 different tissue slide images that had been collected from 100 patients seen at UPMC who were suspected of having prostate cancer. It even spotted six potentially malignant slides that expert pathologists had failed to identify initially.

This interested me, so I contacted the company that developed the algorithm, Israel-based Ibox Medical Analytics. We ran our own validation studies on 1,301 digitized prostate tissue slides and found results similar to those at UPMC. Overall accuracy was 99.4% with 96.9% specificity and 96.5% sensitivity.

How have you integrated AI into your pathology lab?

Our pathologists continue to read digitized images for every prostate tissue slide prepared by our

lab. But starting in June, we also began sending digitized images of each slide to the Ibex cloud. Ibex runs its AI-based algorithm on each slide which provides 100% quality control on all prostate cases. This serves as a digital second opinion for our pathologists.

What happens when there is a discrepancy between the pathologist's exam and the algorithm?

The pathologist goes back and reviews the slide(s) and/or orders an immunohistochemistry. I believe that we have reduced the potential for a misdiagnosis on prostate cancer biopsies to much less than 1%. This is significant given that even an expert uropathologist can miss 3%. So the AI algorithm is acting as a failsafe that is catching cases that might otherwise be missed.

Was there any reluctance from your pathologists as you transitioned to digital pathology and AI for prostate?

The pathologists were always fully engaged in the transition. Our pathologists say they would never go back to the microscope, especially given their ability to read digitized slides at home during the pandemic. We have analyzed over 1,000 prostate biopsy cases using digital pathology with AI assistance to date. In real world practice it has helped identify lesions that would otherwise have been missed.

Will you apply AI-based algorithms to other cancers?

Yes, we are planning to start using an Ibex algorithm for second reads on all breast cancer cases within the next few weeks.

How does your lab get compensated for using digital pathology and AI to improve accuracy?

We do not get additional compensation and that is the problem with the current CPT-based fee-for-service reimbursement model. AI increases accuracy and reduces utilization of immunohistochemistry and there ought to be some coding mechanism that fairly compensates labs that use it.

In the meantime, the increased efficiency that the combination of digital pathology and AI provides has helped offset the initial technology investment and development cost.

In addition, the increased accuracy at CorePlus through its use of AI should lead to more clients. Knowing that 100% of prostate cancer cases sent to CorePlus are getting an AI second opinion should raise urologists' confidence in our lab.

How will AI affect the practice of pathology over the long term?

After our current use of digital pathology and AI as a second read tool, I anticipate it will progress to be used as a triage tool and finally for primary reads with the supervision of a pathologist. The role of pathologists will evolve away from time at the traditional microscope toward selecting the right AI algorithm to apply to a digitized slide and reviewing results in combination with a patient's medical record to form a diagnosis.

Switching gears, is CorePlus performing Covid-19 PCR testing?

We started Covid-19 PCR testing on the Roche cobas 6800 platform in late April. CorePlus has been on an allocation of seven kits per week (equal to 1,344 tests). To compensate for the test reagent shortage, we began pooled testing for three specimens at a time in July. This has expanded our capacity to about 4,000 tests per week and we are preparing to increase our pool size to six specimens, which will double our capacity to 8,000 tests per week.

How do you see the Covid-19 pandemic ending?

It is not going away any time soon, even with a vaccine. Population immunity may take years.

Survey Reveals Huge Gap Between “Have” and “Have Not” Labs

The latest *Laboratory Economics Covid-19 Survey of Labs* showed that 71% of labs were currently performing Covid-19 PCR testing and another 3% planned to soon add this capability, while 26% were not doing this testing. Those labs that are performing Covid-19 PCR testing reported that they expect their overall test volume (including both Covid and non-Covid testing) this year to increase by an average of 59% with a median of 10%.

The benefits garnered by labs doing Covid-19 PCR testing will soon be enlarged as many labs are in the process of switching to combo tests that detect Covid-19 and influenza A/B from a single patient specimen (CPT 87636). New combo PCR tests for Covid-19, influenza A/B and respiratory syncytial virus (RSV) are also being introduced (CPT 87637).

Meanwhile, the “Have Nots” that do not perform Covid-19 PCR testing are expecting average volume growth of only 1% with a median of 0%. The “Have Nots” surveyed were comprised entirely of local pathology groups and physician-office-based labs.

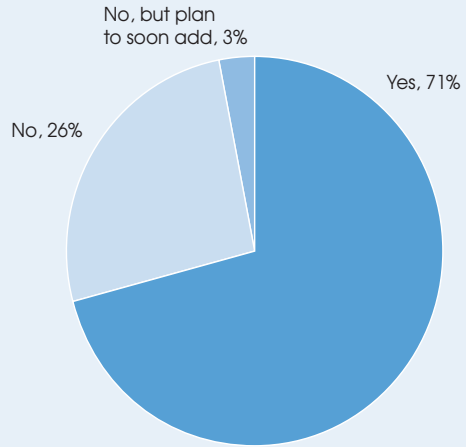
“The downturn in patient office visits has decreased lab volumes and caused many to furlough or completely lay off certain areas of staff. The labs that are thriving are those that have been fast and flexible enough to add Covid testing,” said a surveyed lab executive from Florida.

“The Covid pandemic has introduced new healthcare delivery platforms, such as telemedicine, that do not enable the same amount of referral laboratory testing. Despite offering an electronic order and convenient online scheduling at local patient service centers, we are seeing an increase in patient no-shows and test orders are not being completed,” noted a lab executive from Texas.

National Covid-19 PCR test volumes have quadrupled since *LE’s* initial Covid-19 survey conducted back in early May. Volumes might be even higher if not for continued supply shortages. Our most recent survey showed that 59% of labs had shortages in PCR-based Covid-19 test kits. Pipette tips (45%) and collection swabs/specimen transport media (41%) are also currently in short supply.

The *Laboratory Economics Covid-19 Survey of Labs* was emailed to approximately 6,000 pathologists, laboratory directors, managers and executives between September 30 and October 13. We received complete responses from 124 individuals, including 44% from local independent pathology groups/labs,

Does Your Lab Currently Perform Covid-19 PCR Testing?



Source: *Laboratory Economics Covid-19 Survey of Labs* (October 2020; n=124)

Is your lab experiencing a shortage in any of the following supplies?

	Oct. 2020	May 2020
PCR-based Covid-19 test kits/reagents	59%	47%
Pipette Tips	45%	NA
Collection swabs and/or specimen transport media	41%	58%
Personal Protective Equipment (masks, gloves, gowns, et al.)	27%	57%
Nucleic Acid Extraction Kits	20%	NA
Routine test kits/reagents	20%	14%
Hand sanitizer and/or surface cleaners	0%	3%

Source: *Laboratory Economics Covid-19 Survey of Labs* (October 2020 and May 2020)

25% from national pathology/commercial lab companies, 23% from hospital-based labs and pathology groups, 6% from academic medical centers, and 2% from physician office labs.

The Biggest Long-Term Challenges That Labs and Pathology Groups Face

We also asked surveyed lab executives and pathologists what they saw as the biggest challenges they would face over the next 3-5 years. The top answer was no surprise. Declining reimbursement has consistently been the top concern for labs and pathologists since *LE* conducted its very first survey back in 2007.

Exclusion from managed care contracts has also consistently been a top concern over the years.

Meanwhile, concern over prior authorization test order requirements has been growing fast. The percentage citing it as a top challenge jumped to 38% this year, from 28% in 2019, 13% in 2016 and just 6% in 2015.

Technical staff shortages, cited this year by 34%, are also a growing challenge.

Only 27% of surveyed labs and pathologists saw the current Covid-19 pandemic as a challenge that would continue for the next 3-5 years.

Below are some of the comments we received from survey takers.

“Insurance is a nightmare. Prior authorization and the willingness to harm their own policy holders is a clear fact and these folks need to be cautioned,” according to a lab executive from Michigan.

“Once again, the private insurance companies are not playing by the rules, which is making it hard to get paid for lab work. This comes at a time when labs are struggling with a shortage in testing supplies and PPE along with the added expense of managing a lab during Covid pandemic,” said a lab manager from Georgia.

“Decreasing volumes, algorithms to limit test ordering, and payer pre-authorization requirements for many tests are each a challenge,” according to a pathologist from Tennessee.

What are the biggest challenges that labs and pathology groups will face over the next 3-5 years?*					
	2020	2019	2016	2015	2014
Declining reimbursement	81%	82%	89%	74%	93%
Exclusion from managed care contracts	44%	47%	45%	41%	32%
Prior authorization test order requirements	38%	28%	13%	6%	NA
Technical staff shortages	34%	28%	21%	11%	11%
Competition from large commercial labs	28%	42%	36%	36%	37%
The Covid-19 pandemic.....	27%	NA	NA	NA	NA
Specialty physician groups insourcing pathology	16%	25%	36%	30%	32%
Increased expenses for information technology	14%	14%	13%	17%	23%
Difficulty/expense of adding new molecular tests	6%	14%	12%	14%	13%
Pathologist shortages	3%	11%	6%	2%	7%

*Survey participants were asked to pick their top three challenges
Source: *Laboratory Economics Surveys* (October 2020, July 2019, August 2016, July 2015 and January 2014—no comparable *LE* surveys were conducted in 2017 and 2018)

Medicare Cuts Rate For Covid-19 PCR Tests For Labs With Long Turnaround Times

On October 15, CMS said it would cut the reimbursement rate for high-throughput Covid-19 PCR tests to \$75 from \$100, effective January 1, 2021. However, Medicare will also adopt an add-on payment of \$25 for tests run on the high-throughput platform if the lab both 1) completes the specific test within 2 days of specimen collection, and 2) completes the majority of its tests (not just Medicare) within 2 days.

Spotlight Interview with Diagnostic Laboratories of Oklahoma's Dennis Hogle

Diagnostic Laboratory of Oklahoma (DLO) was formed in 2001 as a joint venture between Quest Diagnostics and INTEGRIS Health. The laboratory serves more than 3,500 physicians and 75 hospitals throughout Oklahoma. Laboratory Economics recently spoke with DLO Chief Executive Dennis Hogle about how his laboratory is faring during the Covid-19 pandemic.



Dennis Hogle

How many Covid-19 PCR tests is DLO doing per day?

We have the capacity to run up to 2,300, but we're currently averaging 1,500 a day.

We also have access to much more testing through our parent company, Quest Diagnostics. We have sent tests to Quest, for example, if we have an instrument issue or if we hit our max.

Have you been able to meet demand for testing?

Early on, it was difficult to meet demand due to shortages of supplies and equipment. Currently, DLO is able to meet demand and in most cases is exceeding the expectations.

What analyzers do you use?

Locally, we operate Panther, Cepheid and QuantStudio DX platforms, but once again, we have access to a much broader array of analyzers through Quest.

What is your average turnaround time?

We currently are reporting an average turnaround time of two days or less (from receipt in the lab) across all populations. Average turnaround time for our priority population, which includes hospitalized patients, individuals in long-term care (such as nursing homes), and presurgical patients, is slightly above one day.

Which supplies (if any) are in short supply?

We are holding good on all supplies, but it is closely monitored.

Is DLO doing pooled sample Covid-19 testing?

Currently, DLO is not performing pooled testing as the positivity rate is a critical factor in pooling and the rate is too high in Oklahoma (it's been running around 9%). It makes mathematical sense to do pooling if you are at 4% or less in terms of positivity rate.

How many antibody tests do you do per day?

We are averaging 125 a day, but we have the capacity to perform on average 2,500 per day. At this time, we are not seeing a demand for the testing, but we are prepared should that change.

Have non-Covid-19 test volumes bounced back?

Our core business dipped by around 45% in April, but we have since rebounded and are currently down only a few percentage points. We were pleased to see how quickly Oklahoma rebounded when compared to other states.

Have you had to lay off or furlough any employees?

At the end of March, when the physician offices began closing and the hospitals canceled elective surgeries, my leadership team quickly put a plan in place which included a voluntary furlough of 125 employees and an additional 55 employees accepting hour reductions. We fully expected this period to last up to 12 weeks but were pleased when we had to begin calling employees back to work within two weeks to accommodate the volume increases. All 700 of our employees returned to their normal schedules by mid-July and we have since opened numerous new positions to accommodate our increased workload.

How big a hit is the pandemic having on DLO's revenues?

Had you asked this question in April I would be providing a very different answer, but I am pleased to report that we have fully rebounded and now expect to exceed our budgeted revenues.

How do you see the Covid-19 pandemic changing the lab industry over the longer term (three to five years)?

We have proven that it is possible to bring up new assays in record time, that new supply chains can be formed as companies reinvented themselves to supply masks, gowns, etcetera, and that the workforce can be even more productive through the use of virtual meetings. We have found that numerous employees can productively work remotely, which will reduce the need for office space. In addition, the sales force has redirected their previous in-person calls toward texts, emails, phone calls and Zoom meetings depending on each client's preference.

How has COVID impacted your community?

Many patients chose not to seek medical attention during the pandemic, so there were a number of illnesses, such as cancer, that went undiagnosed for a few months. I am on the board of the American Cancer Society for Oklahoma, New Mexico and West Texas. The biggest problem we face right now is the lack of charitable giving, which is hurting our ability to fund research projects. That will impact cancer going forward.

CMS Sends Cease-And-Desist Letters To 171 Covid-19 Testing Labs

The Centers for Medicare & Medicaid Services (CMS) says that it has issued cease-and-desist letters to 171 facilities across the U.S. that were testing for Covid-19 without appropriate Clinical Laboratory Improvement Amendments of 1988 (CLIA) certifications. Of the 171 letters, 34% went to facilities conducting lab testing without a CLIA certificate and 66% were issued to labs performing Covid-19 testing outside the scope of their existing CLIA certification. The letters ordered these labs to stop immediately and provided non-certified labs with information on how to become CLIA certified and encouraged certified laboratories to obtain the proper CLIA certification to resume testing.

BioReference Settles False Claims/Kickback Allegations For \$11.5 Million

The U.S. Attorney for the Southern District of New York has reached an \$11.5 million settlement with BioReference Labs (Elmwood Park, NJ) that resolves allegations that BioReference engaged in fraudulent billing practices and received kickbacks from 2009 to 2012. The settlement covers allegations that BioReference fraudulently billed Medicare and Tricare for testing that it performed on hospital inpatients when it should have billed the hospitals directly. In addition, the settlement covers charges that BioReference paid a percentage of the cost of electronic medical records software to 69 doctors' offices, based on the volume of business the offices generated, in violation of the anti-kickback statute. The government's case was prompted by two separate whistleblower complaints filed by a former BRL sales rep and two managers in 2010. BioReference was acquired by Opko Health in 2015.

HNL Lab Medicine Acquires Small Nursing Home Lab

HNL Lab Medicine (formerly named Health Network Laboratories) has acquired Northeastern Laboratory Medicine of Hazleton (NLM Labs). Founded in 1983, NLM Labs is a small independent lab with approximately 25 employees that specializes in clinical lab testing for nursing homes and home-bound patients. Based in Allentown, Pennsylvania, HNL Lab Medicine has approximately 1,100 employees and is owned by Lehigh Valley Health Network.

Lab Stocks Jump 52% Year To Date

Twenty one lab stocks have risen by an unweighted average of 52% year to date through October 16. In comparison, the S&P 500 Index is up 8% so far this year. The top-performing lab stocks thus far in 2020 are Aspira Women's Health (formerly named Vermillion), up 383%; Opko Health, up 192%; and Invitae, also up 192%. Shares of LabCorp are up 18%, while Quest Diagnostics is up 13%.

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)	\$199.09	\$169.17	18%	\$25,950	2.3	18.1
Sonic Healthcare (SHL.AX)*	36.40	28.75	27%	20,720	3.1	14.6
Quest Diagnostics (DGX)	120.20	106.79	13%	20,020	2.7	13.5
Exact Sciences (EXAS)	103.32	92.48	12%	15,990	14.1	NA
Guardant Health (GH)	101.00	78.14	29%	9,290	36.1	NA
Invitae (NVTA)	47.03	16.13	192%	8,410	36.1	NA
Natera (NTRA)	71.08	33.69	111%	5,680	16.6	NA
NeoGenomics (NEO)	43.19	29.25	48%	4,780	11.8	281.9
Opko Health (OPK)	4.30	1.47	192%	3,140	3.3	NA
CareDx (CDNA)	51.56	21.57	139%	2,330	15.6	NA
Veracyte (VCYT)	42.82	27.92	53%	2,250	20.0	NA
Myriad Genetics (MYGN)	12.85	27.23	-53%	1,010	1.6	NA
Castle Biosciences (CSTL)	49.97	34.37	45%	884	14.1	80.8
Progenity (PROG)	9.03	15.00	-40%	378	5.2	NA
Aspira Women's Hlth (AWH)	3.91	0.81	383%	337	73.8	NA
DermTech Inc. (DMTK)	11.19	12.40	-10%	166	33.6	NA
Exagen (XGN)	15.93	25.40	-37%	164	4.2	NA
Enzo Biochem (ENZ)	2.15	2.63	-18%	75	1.0	NA
Interpace Biosciences (IDXG)	4.01	5.00	-20%	55	2.0	NA
Biocept (BIOC)	4.70	2.90	62%	43	7.5	NA
Psychemedics (PMD)	4.35	9.15	-52%	30	1.0	NA
Unweighted Averages			52%	\$121,701	14.5	81.8

*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 50 Countries (October 18, 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>
Peru	33.0	31	78%	20%	865,549	33,702	1,018
Belgium	11.6	42	98%	22%	213,115	10,392	896
Spain	46.8	45	80%	24%	982,723	33,775	722
Brazil	212.7	33	88%	22%	5,224,362	153,690	722
Chile	19.1	34	88%	28%	490,003	13,588	709
Ecuador	17.7	28	64%	20%	152,422	12,375	698
United States	331.2	38	82%	42%	8,343,244	224,284	676
Mexico	129.1	29	84%	29%	847,108	86,059	665
United Kingdom	67.9	40	83%	28%	705,428	43,579	641
Italy	60.5	47	71%	20%	402,536	36,474	604
Sweden	10.1	41	88%	21%	103,200	5,918	585
Argentina	45.3	32	92%	28%	979,119	26,107	576
Columbia	51.0	31	81%	21%	952,371	28,803	564
France	65.3	42	82%	22%	867,197	33,392	511
Netherlands	17.1	43	92%	21%	220,052	6,737	393
Ireland	4.9	38	63%	25%	48,678	1,849	373
Iran	83.7	32	76%	26%	530,380	30,375	360
South Africa	59.3	28	67%	28%	702,131	18,408	309
Bahamas	0.393	32	86%	32%	5,628	116	294
Canada	37.7	41	81%	29%	196,321	9,746	258
Switzerland	8.7	43	74%	20%	74,422	2,123	245
Israel	8.6	30	93%	26%	302,911	2,202	239
Russia	145.9	40	74%	23%	1,399,334	24,187	166
Saudi Arabia	35.0	32	84%	35%	341,854	5,165	148
Germany	83.9	46	76%	22%	361,733	9,853	117
Denmark	5.8	42	88%	20%	35,392	680	117
Turkey	84.5	32	76%	32%	345,678	9,224	109
Austria	9.0	44	57%	20%	64,806	893	99
Poland	37.8	40	60%	23%	175,766	3,573	94
India	1,380.7	28	35%	4%	7,494,551	114,064	82
Morocco	37.0	30	64%	26%	170,911	2,878	78
Finland	5.5	43	86%	22%	13,424	351	63
Egypt	102.3	25	43%	32%	105,297	6,109	59
Norway	5.4	40	83%	23%	16,369	278	51
Indonesia	273.5	30	56%	7%	361,867	12,511	46
Australia	25.5	38	86%	29%	27,391	904	35
Bangladesh	164.7	28	39%	4%	388,569	5,660	34

Country	Population (millions)	Median Age	% Urban Population	% Pop Obese	Total Cases	Total Deaths	Deaths/1M Pop
Iceland	0.342	38	94%	22%	3,998	11	32
Pakistan	220.9	23	35%	9%	323,019	6,654	30
Sudan	44.0	20	35%	7%	13,691	836	19
Kenya	54.1	20	28%	7%	44,196	825	15
Japan	126.5	48	92%	4%	92,063	1,661	13
Ethiopia	115.0	19	21%	5%	88,434	1,346	12
South Korea	51.3	44	80%	5%	25,199	444	9
Malaysia	32.5	30	78%	15%	20,498	187	6
Singapore	5.9	42	99%	6%	57,911	28	5
New Zealand	5.0	38	87%	31%	1,886	25	5
Nigeria	206.1	18	52%	9%	61,307	1,123	5
China	1,439.3	38	61%	6%	85,672	4,634	3
Vietnam	97.6	33	37%	2%	1,134	35	0.4
Avg. for High Median Age Countries (>35)	104.4	42	81%	21%	580,714	18,232	269
Avg. for Low Median Age Countries (<35)	140.3	28	63%	19%	832,520	22,882	272
Avg. for High Urban Pop Countries (>80%)	52.8	38	87%	24%	841,931	27,517	357
Avg. for Low Urban Pop Countries (<80%)	191.9	32	57%	16%	571,303	13,596	183
Avg. for High Obesity Countries (>20%)	56.6	36	80%	26%	800,249	25,818	361
Avg. for Low Obesity Countries (<20%)	239.2	32	58%	9%	540,160	11,203	108
Totals Worldwide	7,794.8	31	56%	13%	40,024,355	1,115,605	143

Source: World Health Organization and Worldometer (October 18, 2020)