

LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

MedPAC Meeting Should Raise Red Flags For Future Of CLFS Rates

The influential Medicare Payment Advisory Commission (MedPAC) held a meeting on September 3 to review the methodology CMS used to set private-payer-based rates for Medicare’s Clinical Laboratory Fee Schedule (CLFS). During the meeting, commission members discussed a variety of new methods that could be used to reduce the burden on labs that must collect and report their private-payer lab test rates to CMS. The American Clinical Laboratory Association (ACLA) and its largest members have been lobbying for the switch to a statistical sampling method that fairly represents each lab segment, especially hospital labs, so that the low prices from largest independent labs are not over-represented. However, the discussion at the MedPAC meeting seemed to lean in the exact opposite direction. *Continued on page 11.*

First U.S. Lab Implements AI Solution for Prostate Cancer

It looks like CorePlus Laboratorio Clinico (Carolina, Puerto Rico), a CLIA-certified anatomic pathology lab, has become the first independent lab in in the Americas to begin using artificial-intelligence-assisted pathology for prostate cancer diagnostics. CorePlus says it has begun digitizing traditional glass slides and analyzing them with Galen Prostate, an AI-based system for prostate cancer detection made by Ibex Medical Analytics (Israel). CorePlus says its validation studies on 1,301 digitized prostate tissue slides showed overall accuracy of 99.4% with 96.9% specificity and 96.5% sensitivity. CorePlus says it has already reported in excess of 500 prostate cases using AI. For more on the outlook for AI-assisted pathology, *see pages 4-5.*

Will Genetic Testing Bust Medicare?

Despite claims denial rates that average 50%, Medicare Part B spending on genetic tests jumped by 79% to \$1.1 billion in 2018. In a newly issued report, the Office of Inspector General (OIG) cited genetic tests as a key factor contributing to the overall 7% increase in Medicare spending on clinical lab tests in 2018, which occurred despite 10% PAMA rate cuts for most high-volume routine tests. The soaring trend in genetic test spending very likely continued in 2019 and 2020 as the number of genetic tests listed on the CLFS or given Proprietary Laboratory Analyses (PLA) codes increased from 289 tests in 2018 to 477 tests as of September 2020, notes *Laboratory Economics*. The OIG report said that “given how expensive many of these tests are, even a small number of inappropriate tests could expose Medicare to extremely high spending.” *Continued on page 2.*

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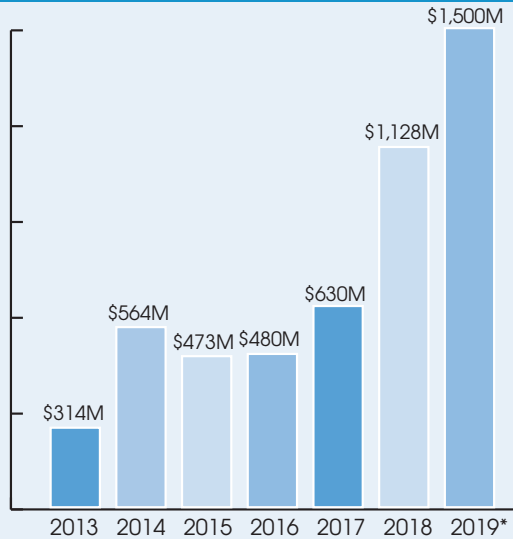
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Will Genetic Testing Bust Medicare? (cont'd from page 1)

“As spending on genetic tests and the volume of these tests continue to grow, oversight of these tests becomes more important. OIG will continue to monitor payments for genetic tests and encourages CMS to continue oversight efforts to identify and prevent improper payments,” according to the OIG report (*Medicare Laboratory Test Expenditures Increased in 2018, Despite New Rate Reductions*—1 OEI-09-19-00100).

Medicare Part B Carrier Spending on Genetic Tests



*Estimated by Laboratory Economics
Source: Laboratory Economics from Medicare Part B National Summary Data Files, 2013-2018

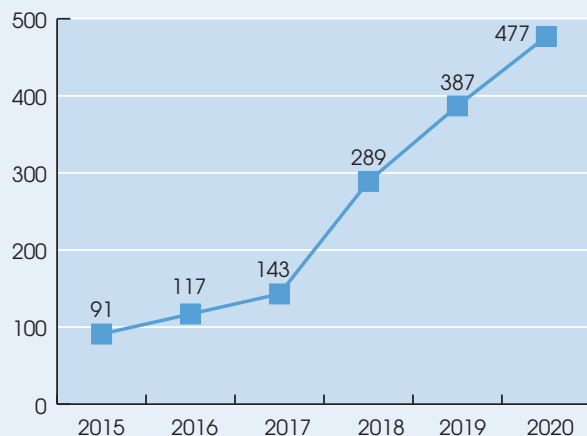
The OIG report also noted that spending on automated chemistry tests increased because the Automated Test Panel (ATP) discount that CMS had previously applied to these tests prior to 2018 was not allowed under PAMA. However, the removal of the ATP discounting system has become less relevant following the three straight years of 10% rate cuts applied under PAMA to most automated chemistry tests in 2018-2020, notes *Laboratory Economics*.

The biggest factor contributing to the growth in Medicare spending on lab tests is genetic testing. Genetic testing comprised 9% of the overall \$7.1 billion that Medicare Part B spent on clinical lab tests in 2017. That percentage increased to 15% of the total \$7.6 billion Medicare spent on clinical

lab tests in 2018, and then to an estimated 20% of the \$7.5 billion spent in 2019. If current trends continue, genetic testing will rise to represent more than one third of overall Medicare lab spending by 2022.

Exact Sciences' Cologuard (CPT 81528) was the top genetic test based on Medicare Part B spending. Medicare Part B spending on Cologuard increased by 44% to \$167.2 million in 2018. Colo-

Number of Genetic Test Codes on CLFS*



*Includes all Molecular Pathology Tests, Multianalyte Algorithmic Assays, Genomic Sequencing Procedures and Proprietary Laboratory Analyses codes (as of September 2020).
Source: Laboratory Economics from Medicare CLFS 2015-2020.

guard, a screening test for colorectal cancer, has a current CLFS rate of \$508.87.

The fastest-growing genetic test in 2018 was CPT 81599 (Unlisted Multianalyte Assay with Algorithmic Analysis), up 3,551% to \$12.3 million. The average allowed payment rate for CPT 81599 is \$4,006.

CPT 81201 (APC Gene Analysis), grew by 2,227% to \$29.8 million. The 2020 CLFS rate for CPT 81201 is \$780.

Spending on CPT 81408 (Molecular Pathology Procedure, Level 9) rose 1,190% to \$120.7 million. The 2020 CLFS rate for CPT 81408 is \$2000.

Medicare Part B Spending For Top 25 Genetic Tests, 2018 vs. 2017

HCPCS	Short Description (Brand Name)	2020 CLFS Rate	2018 Part B Spending	2017 Part B Spending	% Chg
81528	Genetic Test Analysis, Colorectal Cancer (Cologuard)	\$508.87	\$167,191,703	\$116,384,403	44%
81479	Unlisted Molecular Pathology Procedure	1,478.35*	132,638,865	113,196,014	17%
81408	Molecular Pathology Procedure, Level 9	2,000.00	120,688,407	9,358,575	1,190%
81519	Genetic Test Analysis, Breast Cancer (Oncotype DX)	3,873.00	76,642,691	59,957,827	28%
81162	BRCA 1&2 Gene Analysis	1,824.88	49,860,043	51,424,587	-3%
81490	Biomarker Testing for Rheumatoid Arthritis (Vectra DA)	840.65	34,359,408	26,308,681	31%
0037U	Targeted Genomic Sequence Analysis (FoundationOne CDx)	3,500.00	32,728,869	0	NA
81317	PMS2 Gene Analysis	676.50	31,588,686	2,760,857	1,044%
81493	Coronary Artery Disease Gene Expression (Corus CAD)	1,050.00	29,940,566	28,814,029	4%
81201	APC Gene Analysis	780.00	29,785,160	1,279,964	2,227%
81298	MSH6 Gene Analysis	641.85	26,307,256	2,223,242	1,083%
81545	Thyroid Gene Expression Analysis (Afirma Gene Expression Classifier)	3,600.00	22,337,668	16,515,145	35%
81406	Molecular Pathology Procedure, Level 7	282.88	21,850,413	16,789,324	30%
81455	Targeted Genomic Sequence Analysis Panel	2,919.60	21,277,194	2,731,848	679%
81539	Prostate Cancer Probability Panel (4Kscore)	760.00	18,998,215	14,737,138	29%
81595	Heart Transplant Gene Expression Profiling (AlloMap)	3,240.00	18,054,755	12,711,643	42%
81226	CYP2D6 Gene Analysis	450.91	17,247,075	11,720,660	47%
81295	MSH2 Gene Analysis	381.70	15,900,312	1,273,961	1,148%
81432	Hereditary Breast Cancer-Related Disorders	679.05	15,880,652	10,924,394	45%
81541	Prostate Cancer Gene Expression Profiling	3,873.00	15,704,379	0	NA
81211	BRCA 1&2 Full Gene Sequencing	NA	14,797,625	8,360,556	77%
81599	Unlisted Multianalyte Assay with Algorithmic Analysis	4,005.75*	12,309,679	337,187	3,551%
81404	Molecular Pathology Procedure, Level 5	274.83	10,844,908	5,542,181	96%
81521	Breast Cancer Microarray Gene Expression (MammaPrint)	3,873.00	10,581,631	0	NA
81401	Molecular Pathology Procedure, Level 2	137.00	10,291,479	13,531,334	-24%
	Total for Top 25 Genetic Tests		\$957,807,638	\$526,883,550	82%
	Grand Total for All Genetic Tests		\$1,127,942,847	\$630,386,189	79%

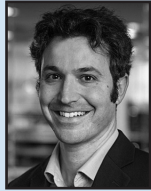
*2020 rates for unlisted test codes 81479 and 81599 are based on average allowed payment rates for 2018.

Note: Grand total includes sum of Medicare Part B carrier payments for all Molecular Pathology Procedures, Tier I & II (CPT 81105-81409), Genomic Sequencing Procedures (CPT 81410-81471), Multianalyte Algorithmic Assays (CPT 81490-81599) and all Proprietary Laboratory Analyses (PLA) codes.

Source: *Laboratory Economics* from Medicare Part B National Summary Data Files, 2017-2018

The Outlook For Artificial-Intelligence-Assisted Pathology

More than a dozen startups, as well software giants Google and IBM, are developing pattern-recognition algorithms (aka artificial intelligence tools) to help pathologists detect and quantify cancerous cells from digitized biopsy specimens. For insight on what the future holds for AI-assisted pathology, *Laboratory Economics* spoke with Andy Beck, MD, PhD, a pathologist by



*Andy Beck,
MD, PhD*

training who is cofounder and Chief Executive of PathAI (Boston, MA). With 150 employees and partnerships with numerous pharmaceutical firms, IVD manufacturers and laboratories, PathAI is among the leaders working on AI-based technologies to help pathologists make quicker and more accurate diagnoses.

Can you describe the genesis of PathAI?

In 2016, myself and PathAI cofounder and Chief Technology Officer Aditya Khosla, PhD, led a team of scientists from Harvard and MIT that won the Cancer Metastases in Lymph Nodes Challenge 2016 [Camelyon16]. We competed against 22 other teams from around the world. Each team was given the same labeled training data—270 digitized slides from patients with and without cancer. The goal was to develop an AI algorithm to correctly identify cancer in a new set of digitized slides. Teams competed against each other as well as a panel of 11 pathologists using traditional light microscopes.

Our algorithm won the competition among the models with an overall accuracy of 92.5%. This was less than the 96.5% achieved by the pathologists. However, when our algorithm was combined with a pathologist's review, the accuracy increased to 99.5%.

Shortly thereafter we started PathAI.

How much capital has PathAI raised?

We raised \$15 million in 2017 and another \$75 million in late 2019. Among our largest venture capital investors are General Atlantic and General Catalyst. Strategic investors include Bristol-Myers, Merck and LabCorp.

Do your AI algorithms continually improve as you feed more labeled images into them?

Yes. Our algorithms are continuously getting better with more data. Our system learns much the same way that a pathology student is trained—by viewing labeled images and recognizing patterns. But our system can learn from thousands and thousands of examples, while there are limits to the number of cases a single pathologist will see in training or even over the course of their entire career.

How many labeled digitized slides do you have access to and where do they come from?

We have access from our many partners, including academic medical centers, cancer centers, laboratories and pharmaceutical companies, throughout the country. In total, we have trained our system on over 5 million annotated pathology images to date.

What differentiates PathAI from other companies developing AI tools for pathology?

Our platform has now generated novel insights across a broad range of cancer types (including non-small cell lung cancer, bladder cancer, melanoma, head and neck squamous cell carcinoma, breast cancer) and liver diseases (including: primary sclerosing cholangitis, hepatitis B, and non-alcoholic steatohepatitis). The breadth and power of our platform for enabling new insights differentiates our company from others in the field.

For which cancers have you developed algorithms?

We've now developed research algorithms for detection and quantitative IHC scoring for nearly all solid tumors, including bladder, breast, colorectal, gastric, lung and prostate cancers, with high accuracy and perfect reproducibility. For example, our AI algorithm for breast cancer has improved to 99.6% accuracy from the 92.5% we achieved four years ago at the initial completion of the Camelyon16 competition.

What do AI algorithms do better than human pathologists?

Computers can quickly and exhaustively look at every single image and count every cell on a digitized slide. Pathologists are under time constraints and often required to make judgement calls. So while there can be discordance among pathologists viewing the same case, AI algorithms produce accurate, scalable, uniform and reproducible results.

So will pathologists become obsolete in the future?

Artificial intelligence won't replace pathologists; it will assist them by taking on the most repetitive low-level tasks, such as counting cancer cells and prefiling pathology reports. This will free pathologists to spend more time on their most complex cases. Among the things that AI can't do is integrate heterogeneous pieces of information from a patient's clinical lab tests, pathology stains and medical record to develop a big-picture clinical judgement.

What kind of productivity gains can be expected from AI-assisted pathology?

We are currently working on better defining the magnitude of productivity gains. At a high level once further developed and validated for specific use cases and clinical workflows, we expect an AI-assisted pathologist should be able to increase their efficiency by at least 50%.

To date, labs and pathologists have been slow to adopt digital pathology. Isn't this a barrier to their adoption of AI tools?

The clinical benefits of using digital pathology haven't yet been big enough to outweigh the added cost of scanners, extra personnel, data storage, etc. But the introduction of new AI tools that increase accuracy and pathologist efficiency will make the investment in digital pathology worth it and drive adoption over the next few years.

Will the advent of the "liquid biopsy" eliminate the need for biopsies and related AI tools?

I expect liquid biopsies to be used primarily for cancer screening, but they won't eliminate the need for a tissue biopsy and pathologist interpretation.

When will we start seeing AI tools being used by pathologists in clinical practice?

Our AI tools for roughly 50 immunohistochemistry (IHC) biomarkers are already being used by pharmaceutical companies, such as Bristol-Myers, Genentech, Gilead and Merck, to generate new insights into the pathological basis of treatment response and resistance.

Within the next 12 months, I think you'll begin seeing a variety of AI tools coming to the clinical market from PathAI and other vendors through both the FDA clearance process and as laboratory-developed tests. Broadly speaking, the areas most ripe for AI tools include cancer detection (e.g., metastatic cancer detection), quantitative IHC in cancer (e.g., HER2, Ki67, PD-L1, etc.) and cancer grading (e.g., prostate, breast, etc.).

Outside of cancer diagnostics, are there any other areas in medicine that your AI platform might be used?

In the future, the platform we are developing could be extended to other areas of medicine where images play a critical role in diagnosis and treatment planning, including radiology.

Spotlight Interview with University of Texas Medical Branch's Michael Laposata

University of Texas, Medical Branch, a system of care that includes hospitals and emergency departments on four campuses, along with a primary and specialty-care clinics, urgent care and walk-in services, serves Galveston and Southeast Texas. *Laboratory Economics* recently spoke with Michael Laposata, MD, PhD, Chairman of the Department of Pathology, about Covid-19 testing and the impact of the pandemic on the organization.



Michael
Laposata,
MD, PhD

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

Right now, we are doing about 1,000 per day. We started on March 13. At our peak in April and May, we were doing up to 3,500 per day. We have capacity to do close to 4,000 per day. Altogether, we have performed about 180,000 Covid-19 PCR tests. In addition to not looking because you might find it, I am surprised there isn't more demand. For any Covid test down the road, there is a focus first on quick, second on inexpensive, third on simplicity, and fourth on whether the result is correct. Clearly the fourth one should be the top priority.

Which supplies (if any) are in short supply?

We've had challenging times from the beginning with Cepheid; we weren't getting enough reagents. Also, our big supplier, Hologic, from time to time has been slowing down supplies in our direction because there appears to be a high level of purchasing of reagents from companies that are doing just Covid work. That's where some of the supplies are going, so we are stuck.

Is UTMB doing pooled sample Covid-19 testing?

No. I don't think it's a good idea. Let's say you are the one person in a pooled sample of 20 who is positive, then you have to retest all 20 again. It adds on to turnaround time. Right now, we can turn Covid-19 PCR tests around in two to three days, sometime even in one day. Several large commercial laboratories are taking 10 to 11 days. A test result that takes that long is not informative.

Which test analyzer do you run most of your Covid-19 tests on?

We have four platforms that we use. Two Abbotts, one Hologic and one Cepheid. The Hologic carries the bulk of the volume. We also have a lab-developed test. When we realized the CDC test was flawed, we set up our own LDT. Our capacity for that is about 700 daily, which we performed on the days when we were going at maximum capacity.

Do you have a recommendation that might help ease the supply shortage for labs?

I don't think there are any obvious answers. Abbott has been great to us. I think Cepheid simply set a production target for the reagents that was just too low.

Have non-Covid-19 test volumes bounced back? Clinical lab tests? Anatomic pathology tests?

We had to stop doing elective surgeries in the spring. In April, volumes of non-Covid tests dropped significantly, but they started bouncing back in May. Test volumes went down to less than half of what was normal, but now we are at about 80% to 90% of pre-Covid levels.

Have you had to lay off or furlough any employees?

We did bring in about \$7 million from Covid-19 testing, but we did have to furlough 105 employees, largely administrative, which is how we made up for the lost volumes. I don't expect the positions will be brought back. We have learned new ways of doing things with fewer people. In the lab, we didn't lose even one.

About how many Covid-19 antibody tests is UTMB doing each day?

We've done about 7,000 IgG antibody tests. We really want the IgM, but we haven't gotten it yet. Demand for antibody testing is way less than expected across the country, because too many doctors didn't understand the clinical meaning of antibody test results. They also didn't know the difference between an antibody and a neutralizing antibody, so the information they provided about whether or not patients had immunity to the Covid-19 virus contained some inaccuracies. Also, there is no clear guidance on what to do with the results. I think a patient would most benefit by having both IgG and IgM antibody results. However, there is little experience with IgM antibodies to Covid-19 nationally.

Do you think Covid-19 will come back in a severe way this fall/winter?

Hard to say, but we will know within a month if the Labor Day weekend made it come back and how badly. Our beaches here in Galveston, Texas were crowded over the holiday.

How will the Covid-19 pandemic change the lab industry over the longer term (three to five years)?

Things we've done that we haven't done before include interacting with the company's scientists directly about test performance. We have been much more thorough because we didn't want to let a poorly performing test in the door. I am very confident in all of the tests that we run in our laboratory.

Spotlight Interview With PathGroup CEO Ben Davis

Originally founded by pathologists in 1965, PathGroup (Brentwood, TN) has grown to become the nation's largest privately-held lab company. PathGroup, which currently has 2,200 employees, is owned by Pritzker Private Capital, company management and pathologists. *Laboratory Economics* recently spoke with long-time Chief Executive Ben Davis, MD, to discuss PathGroup and its growing role in Covid-19 testing.

**When did PathGroup initiate Covid-19 PCR testing and how many are being performed?**

Ben Davis, MD We began Covid-19 PCR testing on April 1st with an initial capacity of 2,000 tests per day using the Hologic Panther and Roche cobas 6800 platforms. We are currently performing an average of about 7,500 tests per day with capacity of up to 14,000 tests per day. Demand is coming from physician clinics, state health departments, employers, schools, universities, hospitals and nursing homes. Peak demand came in early July when we received specimens in excess of our capacity for several days.

How have positivity rates trended?

On July 6 our positivity rate peaked at 17%. That's dropped to a current average of about 10%, including 12.5% for patients under age 30 and 9% for those 30 and above.

What is your turnaround time for Covid-19 PCR testing?

Our turnaround time from specimen collection to result reporting is consistently 24 hours for all clients. We have limited new client additions in order to maintain a 24-hour turnaround time. The location of our main 150,000-square-foot lab—adjacent to Nashville International Airport—has also helped.

Could PathGroup do more Covid-19 PCR tests if it had more supplies?

Yes. The current shortages of specimen collection devices and test kits are keeping us below instrument capacity. We've kept in close touch with our suppliers on changing situations and plan accordingly.

Are most private insurers matching Medicare's \$100 reimbursement rate for Covid-19 PCR testing?

Yes.

Describe the NIH grant that PathGroup was awarded and how it will be used?

PathGroup has received a \$20.75 million grant from the National Institutes of Health (NIH) under its Rapid Acceleration of Diagnostics (RADx) program. The grant funding will be used to purchase new high-throughput liquid handling, robot and automated testing equipment from Illumina, LGC, Hologic and Thermo Fisher. We also plan to hire an additional 100 to 200 employees with the goal of expanding our Covid-19 PCR testing capacity to 80,000 tests per day. Importantly, we'll be diversifying our supply chain to mitigate risk against supply chain constraints as fall/winter approaches.

Which Covid-19 antibody test does PathGroup perform?

Roche's cobas serum antibody test. We're performing about 400 tests per day.

Have non-Covid-19 clinical and pathology test volumes bounced back from the lows?

Yes. In late March/early April, our volumes had declined temporarily by 75% with anatomic pathology case volume hit the hardest. But in May, as physician offices started re-opening and elective surgeries resumed, we saw a sharp rise in non-Covid-19 volumes that are currently back at 100% of pre-pandemic levels, maybe even a little higher.

What precautions have you taken for your employees?

About 15% to 20% of our 2,200 employees are currently working from home. All people entering our lab facilities have their temperature checked and must wear masks. We are also offering Covid-19 testing on a voluntary basis to any employee that requests one, whether symptomatic or asymptomatic.

Do you think Covid-19 will come back in a severe way this fall/winter?

I would not want to predict severity, but the disease is likely to continue to spread this coming fall/winter. A vaccine will help, but Covid-19 is not going away. One of my biggest fears is that the disease will adapt and mutate into a more virulent strain, such as SARS-CoV-1 in 2003 and the MERS-CoV in 2012.

Spotlight Interview With Aegis Sciences CEO Frank Basile

Frank Basile,
MD

Aegis Sciences Corp. (Nashville, TN) performs some 20 million toxicology tests per year, making it one of the nation's largest toxicology labs. On April 15, Aegis launched Covid-19 PCR testing with an initial capacity to perform up to 3,500 tests per day. *Laboratory Economics* recently spoke with Chief Executive Frank Basile, MD, to discuss Aegis and its Covid-19 testing strategy.

How many Covid-19 PCR tests is Aegis currently performing?

We are currently performing an average of about 10,000 tests per day with capacity of up to 30,000 tests per day. We're using the PerkinElmer RNA/DNA extraction system and ThermoFisher's QuantStudio 7 analyzer for testing.

Who are your Covid-19 clients?

We've added over 1,000 new clients over the past 12 weeks, including urgent care centers, surgery centers, nursing homes, doctor's offices, correctional facilities and colleges and universities. We also have state contracts with Tennessee, Louisiana and Oklahoma. We placed a moratorium on new client starts in July in order to maintain a 24-hour turnaround time from specimen pickup to result reporting. This was recently lifted as we have increased capacity.

Are private payers matching Medicare's reimbursement rate of \$100 for Covid-19 PCR testing?

Yes, in the majority of cases. Medicaid, however, in some states is paying significantly below and/or are not credentialing because they insist on an "in-state bricks and mortar" presence which is slightly impractical during the pandemic. Additionally, certain payers are denying claims, paying the patient, or not responding at all. This is a significant problem and appears to be in direct conflict with the CARES Act.

Describe the NIH grant that Aegis was awarded and how it will be used.

Aegis has received a \$6.6 million grant from the National Institutes of Health (NIH) under its Rapid Acceleration of Diagnostics (RADx) program. The grant funding will be used to expand our molecular lab from 3,000 square feet to 18,000 square feet. We'll also be moving to Thermo Fisher's high-throughput KingFisher Flex system for RNA/DNA extraction into the lab. We plan to increase our capacity to 60,000 Covid-19 PCR tests per day by September 30.

In addition, we are developing a multiplexed Covid-19 + Flu A/B assay which will be available early October.

Any plans for pooled testing?

We have looked at it. However, we're currently seeing positivity rates of around 10%, which makes pooled testing less feasible. Pooled testing is best suited for discrete population testing of groups expected to have positivity rates of <5%. Aegis serves clients nationwide that range from pre-surgery testing (low positivity rate) to walk-in clinics and correctional facilities (higher positivity rate). Our lab TAT averages less than 24 hours. Samples would have to be segregated to take advantage of pooled testing, leading to workflow complexity and potentially overall increases in TAT.

Has Aegis experienced any supply shortages?

Supplies haven't been a limiting factor for us. We spent five weeks prior to launch getting our supply chain in order. For example, we diversified key supplies by validating specimen transport media from multiple vendors.

Rapidly finding and retaining good people has been the biggest challenge we have needed to overcome. Over the past 12 weeks we have hired over 200 employees, and will continue to hire more, especially for specimen accessioning and processing positions in the lab. Our current overall employee count is 1,051.

Describe your new Covid-19 antibody test.

On August 31, Aegis launched a Covid-19 antibody test that utilizes dried blood spot specimens. The test allows samples to be taken by fingerstick and should be popular for testing children and others. Samples are sent to our lab without the need for an invasive blood draw or additional processing at the collection site. We validated the test in accordance with FDA Emergency Use Authorization (EUA) requirements and it showed 99.9% specificity and 96.1% sensitivity. Demand for antibody testing has been slow so far, but that is likely to change after a Covid-19 vaccine becomes available. Antibody testing could be used to determine if previous exposure to the virus occurred or to see if an individual that received a vaccine elicited an immune response. We expect this to become an important test later this year and into next year, especially as we bring additional product enhancements to market.

Have your toxicology test volumes bounced back from the lows?

Our toxicology volumes bottomed in mid-April but have since rebounded to approximately 80% to 85% of pre-pandemic levels. I expect we'll be back to nearly 100% of "pre-pandemic" levels sometime by year's end.

Do you think Covid-19 will come back in a severe way this fall/winter?

I expect cases to spike up, along with other respiratory infections, this coming fall and winter, although masking might limit the upsurge.

Publicly-Traded Lab Revenue Falls 1.4% In First-Half 2020

On a combined basis, 20 publicly-traded labs reported a revenue decrease of 1.4% to \$9.8 billion during the first six months of 2020 (after adjusting for acquisitions), according to financial reports collected by *Laboratory Economics*.

Among five national clinical labs (Quest Diagnostics, LabCorp, Sonic, BioReference and Enzo), combined revenue fell by 3.1% (after adjusting for acquisitions). BioReference had the strongest revenue growth, up 18% to \$421.8 million, driven by Covid-19 PCR testing. BioReference processed approximately 2.2 million Covid-19 PCR tests during the first six months of 2020.

Among 15 specialty and genetic testing labs, combined pro-forma revenue increased by 7.3%.

Pro-forma revenue growth was fastest at DermTech, up 98.4% to \$2.4 million. Other fast-growing companies included Castle Biosciences, up 54.9% to \$30.1 million; Guardant Health, up 47.7% to \$133.8 million; and CareDx, up 39.6% to \$80.2 million.

Revenue Growth at 20 Publicly-Traded Lab Companies (\$000)

Company	First-Half 2020	First-Half 2019	Reported Change	Pro Forma Change*
Quest Diagnostics (lab testing only)	\$3,508,000	\$3,684,000	-4.8%	-5.5%
LabCorp (lab testing only)	3,394,700	3,482,900	-2.5%	-3.9%
Sonic Healthcare USA ¹	698,040	595,940	17.1%	3.5%
Opko/BioReference Labs	421,800	357,349	18.0%	18.0%
Enzo Clinical Labs (lab testing only) ²	22,999	23,751	-3.2%	-3.2%
Total, 5 National Clinical Labs	\$8,045,539	\$8,143,940	-1.2%	-3.1%
Exact Sciences	616,689	361,913	70.4%	5.4%
Myriad Genetics ³	257,200	432,000	-40.5%	-40.5%
NeoGenomics	193,007	197,290	-2.2%	-2.2%
Natera	180,484	141,179	27.8%	27.8%
Guardant Health	133,845	90,630	47.7%	47.7%
Invitae Corp.	110,439	94,028	17.5%	17.5%
CareDx	80,181	57,436	39.6%	39.6%
Veracyte	51,826	59,665	-13.1%	-13.1%
Progenity	34,094	104,737	-67.4%	-67.4%
Castle Biosciences	30,133	19,456	54.9%	54.9%
Exagen	18,532	19,734	-6.1%	-6.1%
Psychemedics	10,851	19,111	-43.2%	-43.2%
Dermtech	2,401	1,210	98.4%	98.4%
Biocept	2,216	2,364	-6.3%	-6.3%
Aspira Women's Health	1,966	1,945	1.1%	1.1%
Total, 15 Specialty/Genetic Labs	\$1,723,864	\$1,602,698	7.6%	7.3%
Grand Total, All 20 Lab Companies	\$9,769,403	\$9,746,638	0.2%	-1.4%

*Pro forma change is estimated by *Laboratory Economics* after adjustments for acquisitions.

¹Sonic Healthcare USA revenue for the six months ended June 30, 2020 at constant exchange rate of 1 Australian Dollar equal to 0.72 U.S. Dollar. ²Enzo's revenue is for lab services only for six months ended April 30, 2020.

Source: *Laboratory Economics* from company reports

MedPAC Meeting Should Raise Red Flags (*cont'd from page 1*)

At the end of 2019, the Laboratory Access for Beneficiaries (LAB) Act became law. The LAB Act delayed the reporting period for labs to submit their private-payer data to CMS for the second PAMA survey cycle by one year to first-quarter 2021. A recent amendment to the CARES Act has further delayed the reporting to first-quarter 2022.

The LAB Act also mandated MedPAC to: 1) Review the methodology CMS has implemented for the private payer-based CLFS rates, and 2) Report on the least burdensome data collection process that results in a representative sample of all laboratory market segments. MedPAC must report its findings to CMS and Congressional committees in June 2021.

MedPAC is an independent U.S. federal body comprised of 17 members appointed by the Comptroller General of the United States. MedPAC's Chair is Michael Chernew, PhD, a professor of health policy at Harvard Medical School. Its Vice Chair is Paul Ginsburg, PhD, a professor of health policy at the University of Southern California.

Here are some troubling excerpts from the Sept. 3 MedPAC meeting discussion:

Brian DeBusk, PhD: “We may want to recommend sampling just the larger labs. I noticed in the mailing materials they're about 50% of the volume anyway. And we already have the CMS study that showed that incorporating physician offices and hospitals didn't seem to change the rates that much....This feels like a site neutrality issue to me. We've talked about this for years, about how Medicare should pay similar rates for similar care. This seems like a great opportunity to reintroduce and maintain our position regarding site neutrality....I think using the median from a sample of larger, what we would presume are fairly efficient suppliers, would be the way to go.”

Paul Ginsburg, PhD: “Since the current system uses a median, we really don't have to worry about burdening small labs....We just don't need them in the sample, and we really should go to sampling [the larger labs] as you're suggesting. I don't see why we're not talking about whether we should be sticking at a median or whether Medicare [has] an opportunity to get the services, and with continued access, but for less and should be going to a 30th percentile or something even lower as it probably does in many other areas.”

Meanwhile, another MedPAC member suggested that there needs to be more focus on the real growth driver of Medicare lab spending.

Jonathan Perlin, MD, PhD: “This molecular testing aspect is really the driving force in cost escalation in the future. I fear that frankly the emphasis, as they say, is on the wrong syllable. We need to put it back on what's really going to drive cost in the immediate future....There are now over 75,000 orderable genetic tests and approximately ten new tests are launched daily.”

Liquid biopsy Startup Grail Seeks \$100M From IPO

Grail (Menlo Park, CA) set a preliminary \$100 million target for its IPO, according to documents filed with the Securities & Exchange Commission. The company says that it is ramping up for a planned commercial launch of Galleri in 2021 as a laboratory developed test (LDT). The Galleri blood test detects more than 50 types of cancer from fragments of DNA shed by tumors. Grail is building a lab facility with office and warehouse space in North Carolina's Research Triangle Park. More details in next issue of *Laboratory Economics*.

Theranos' Holmes May Use Insanity Defense

Elizabeth Holmes, the founder of disgraced blood-testing startup Theranos, is reportedly considering using “mental disease” as a defense in her upcoming federal fraud trial (starts October 27). If pathological lying is considered a mental disease, then her strategy may very well work, notes *Laboratory Economics*.

Lab Stocks Up 22% Year To Date

Twenty one lab stocks have risen by an unweighted average of 22% year to date through September 11. In comparison, the S&P 500 Index is up 3% so far this year. The top-performing lab stocks thus far in 2020 are Aspira Women's Health (formerly named Vermillion), up 254%; Opko Health, up 103%; and Invitae, up 102%. Shares of LabCorp are up 7%, while Quest Diagnostics is up 3%.

Company (ticker)	Stock Price 9/11/20	Stock Price 12/31/19	2020 Price Change	Enterprise Value (\$ mill)	Enterprise/ Value Revenue	Enterprise Value/ EBITDA
LabCorp (LH)	\$181.47	\$169.17	7%	\$24,240	2.1	17.0
Quest Diagnostics (DGX)	110.33	106.79	3%	18,990	2.5	12.8
Sonic Healthcare (SHL.AX)*	32.53	28.75	13%	18,920	2.9	23.3
Exact Sciences (EXAS)	76.20	92.48	-18%	11,580	10.2	NA
Guardant Health (GH)	95.65	78.14	22%	8,580	33.3	NA
Natera (NTRA)	59.61	33.69	77%	4,640	13.6	NA
Invitae (NVTA)	32.53	16.13	102%	4,230	18.1	NA
NeoGenomics (NEO)	35.35	29.25	21%	3,940	9.7	232.4
Opko Health (OPK)	2.99	1.47	103%	2,360	2.4	NA
Veracyte (VCYT)	30.61	27.92	10%	1,600	14.3	NA
CareDx (CDNA)	33.05	21.57	53%	1,430	9.6	NA
Myriad Genetics (MYGN)	13.29	27.23	-51%	1,070	1.7	NA
Castle Biosciences (CSTL)	48.60	34.37	41%	809	12.9	74.0
Progenity (PROG)	8.92	15.00	-41%	362	4.9	NA
Aspira Women's Health (AWH)	2.87	0.81	254%	309	67.8	NA
DermTech Inc. (DMTK)	10.23	12.40	-18%	144	29.2	NA
Exagen (XGN)	12.75	25.40	-50%	132	3.4	NA
Enzo Biochem (ENZ)	2.19	2.63	-17%	77	1.0	NA
Interpace Biosciences (IDXG)	3.20	5.00	-36%	50	1.8	NA
Psychemedics (PMD)	4.65	9.15	-49%	32	0.9	NA
Biocept (BIOC)	3.61	2.90	24%	31	5.4	NA
Unweighted Averages			22%	\$103,524	11.8	71.9

*Sonic Healthcare's figures are in Australian dollars

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

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Covid-19 Stats for United States (as of 9/12/20)

<i>State</i>	<i>Population</i>	<i>Median Age</i>	<i>Density (per square mile)</i>	<i>% Pop Obese</i>	<i>Total Cases</i>	<i>Total Deaths</i>	<i>Deaths/ 1 Mill Pop</i>
New Jersey	8,936,570	40	1,215	27%	199,754	16,148	1,807
New York	19,440,500	39	413	26%	476,693	33,109	1,703
Massachusetts	6,976,600	39	894	26%	123,986	9,180	1,316
Connecticut	3,563,080	41	736	27%	54,326	4,480	1,257
Louisiana	4,645,180	37	108	36%	156,174	5,202	1,120
Rhode Island	1,056,160	40	1,021	30%	22,905	1,071	1,014
Mississippi	2,989,260	37	64	37%	89,620	2,685	898
Arizona	7,378,490	37	65	30%	208,128	5,315	720
Michigan	10,045,000	40	178	32%	122,251	6,900	687
Illinois	12,659,700	38	228	31%	259,883	8,505	672
Maryland	6,083,120	39	627	31%	115,533	3,836	631
Delaware	982,895	40	504	32%	18,559	613	624
Pennsylvania	12,820,900	41	287	32%	148,323	7,932	619
Georgia	10,736,100	37	187	32%	290,781	6,287	586
South Carolina	5,210,100	39	173	34%	129,978	3,040	583
Florida	21,993,000	42	410	28%	661,571	12,614	574
Indiana	6,745,350	38	188	34%	104,561	3,437	510
Texas	29,472,300	34	113	33%	686,471	14,345	487
Alabama	4,908,620	39	97	36%	136,703	2,333	475
Nevada	3,139,660	38	29	27%	72,806	1,439	458
New Mexico	2,096,640	38	17	28%	26,563	818	390
Iowa	3,179,850	38	57	36%	73,547	1,216	382
Ohio	11,747,700	39	288	34%	135,477	4,406	375
California	39,937,500	36	256	25%	755,714	14,270	357
Minnesota	5,700,670	38	72	28%	83,588	1,949	342

<i>State</i>	<i>Population</i>	<i>Median Age</i>	<i>Density (per square mile)</i>	<i>% Pop Obese</i>	<i>Total Cases</i>	<i>Total Deaths</i>	<i>Deaths/1 Mill Pop</i>
Colorado	5,845,530	37	56	23%	60,492	1,985	340
New Hampshire	1,371,250	43	153	28%	7,620	434	316
Virginia	8,626,210	38	218	30%	132,940	2,722	316
Arkansas	3,039,000	38	58	35%	67,911	953	314
Missouri	6,169,270	39	90	33%	101,644	1,818	295
Tennessee	6,897,580	39	167	33%	169,859	2,025	294
North Carolina	10,611,900	39	218	32%	183,740	3,023	285
Washington	7,797,100	38	117	28%	81,490	1,991	255
Kentucky	4,499,690	39	114	34%	55,704	1,044	232
Oklahoma	3,954,820	36	58	37%	68,659	899	227
Idaho	1,826,160	36	22	29%	34,950	415	227
Nebraska	1,952,570	36	25	33%	37,841	434	222
North Dakota	761,723	35	11	33%	15,151	167	219
Wisconsin	5,851,750	39	108	32%	86,250	1,197	205
South Dakota	903,027	37	12	32%	16,437	183	203
Kansas	2,910,360	37	36	32%	49,342	520	179
West Virginia	1,778,070	42	74	38%	12,521	265	149
Utah	3,282,120	31	40	25%	56,675	431	131
Montana	1,086,760	40	7	25%	8,925	133	122
Oregon	4,301,090	39	45	29%	28,865	499	116
Maine	1,345,790	45	44	29%	4,834	135	100
Vermont	628,061	43	68	28%	1,677	58	92
Wyoming	567,025	37	6	29%	4,297	42	74
Hawaii	1,412,690	39	220	24%	10,459	96	68
Alaska	734,002	34	1	34%	6,113	43	59
Total, 50 States	330,598,493	38	93	39%	6,458,291	192,642	583

Source: CDC and worldpopulationreview.com