Celebrating 15 Years

Volume 15, No. 2 February 2020

LABORATORY ECONOMICS

Competitive Market Analysis For Laboratory Management Decision Makers

Quest To Buy Memorial Hermann Outreach Lab Business

Quest Diagnostics has reached a definitive agreement to acquire select assets which constitute substantially all the operations of Memorial Hermann Diagnostic Laboratories (MHDL), the clinical outreach laboratory business of Memorial Hermann Health System (Houston). The acquisition includes about 30 MHDL patient service centers and nearly 60 in-office phlebotomy service sites. MHDL is one of the largest hospital-based lab outreach businesses in the nation. The deal is expected to be completed by mid-year. *Full details on pages 7-8.*

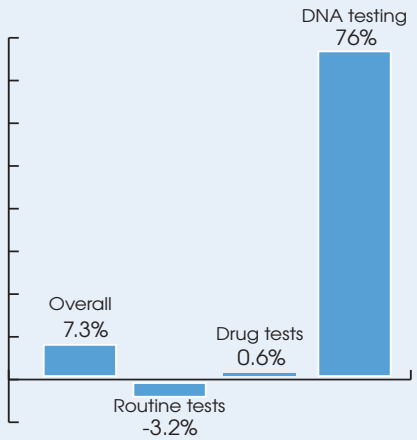
Enzo Delays Shareholder Meeting; Harbert Files Lawsuit

Enzo Biochem (New York City) has delayed its annual shareholder meeting, originally scheduled for January 31, until February 25. The move comes as Enzo's executives are engaged in a bitter battle with the Alabama investment firm Harbert Discovery Fund (HDF) over board seats and the strategic direction of the company. *Cont'd on page 6.*

Medicare CLFS Spending Jumped In 2018

This was not supposed to happen. Medicare Part B Carrier allowed charges for the top 50 clinical lab tests increased by 7.3% to $4.5 billion in 2018, according to an exclusive analysis of the Part B National Summary Data Files by *Laboratory Economics*. This surprising upturn followed several years of flat growth in Part B lab test spending and occurred despite the first year of PAMA's 10% rate cuts for most high-volume test codes.

Growth in Medicare Part B Allowed Charges for 2018



Source: *Laboratory Economics* from CMS

The growth in lab test expenditures was caused almost entirely by two factors: 1) elimination of the Automated Test Payment (ATP) system, and 2) explosive growth in molecular diagnostic and DNA testing. *Full details on pages 2-3.*

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Medicare CLFS Spending Jumped In 2018 (*cont'd from page 1*)

The Medicare Part B carrier data analyzed by *LE* covers services provided by independent labs and physician offices. It excludes lab testing services provided by hospitals, which are paid by fiscal intermediaries. It also excludes Part C managed care plan spending on lab tests.

The upsurge in Part B CLFS spending for the top 50 lab tests was not caused by volume, which rose by only 0.1% in 2018. It was caused by a 7.2% increase in the average allowed charge to $21.94 per lab test code.

Elimination of ATP System

Prior to the implementation of PAMA's new private-payer-based reimbursement rates in 2018, Medicare's ATP system ensured that any combination of 23 high-volume lab tests (albumin, calcium, cholesterol, glucose, potassium, et al.) and associated panels (comprehensive metabolic, lipid, et al.) could not be reimbursed at more than $16.64. Medicare contractors had used the ATP system for more than 25 years to eliminate duplicative tests and improperly unbundled test panels from lab test claims.

But the ATP system was incompatible with PAMA and had to be abandoned with the new private-payer-based CLFS in 2018. The fear had been that without ATP, unscrupulous labs might game the system by ordering panel tests individually to maximize reimbursement (see *LE*, December 2017). However, separate analysis by XIFIN Inc. and CodeMap show no such malfeasance. "Nobody was gaming the system, otherwise there would have been a noticeable increase in test volumes for the 23 automated tests," notes CodeMap President Charles Root, PhD. He says that Part B volumes for the 23 ATP tests were mostly flat in 2018.

Regardless, XIFIN CEO Lale White notes that on October 7, 2019 Medicare re-established the panel bundling edits under CR 11248 along with a retroactive recoupment for any overpayments going back to January 1, 2019. "Technically, there should be no impact because labs were required to continue to code the panels properly and certainly most labs did."

The situation where the elimination of the ATP system has affected payments is when two or more panel tests are ordered on the same claim. For example, Root notes that prior to 2018 when a comprehensive metabolic panel (CMP) and lipid panel were ordered together they were paid as 16 automated tests ($14.49) plus an HDL cholesterol ($11.24) for a total of $25.73.

During 2018 this same combination was paid as a CMP plus a lipid panel for a total of $29.57 (without ATP adjustments), an increase of $3.84 (up 15%). CMP and lipid panels are among the highest volume tests, so this change had a dramatic impact on overall Part B allowed charges (+$88 million) and payments (+$86 million) in 2018, according to Root. "This really softened the blow of the PAMA rate cuts in 2018, although subsequent rate cuts of 10% each in 2019 and 2020 have eliminated this advantage." For example, this year the combination of a CMP ($10.56) and lipid panel ($13.39) is reimbursed by Medicare at $23.95.

Overall, there were 30 routine tests among the top 50. Allowed charges for routine tests decreased by 3.2%. Volume declined by 0.4% and average allowed charge fell by 2.7% to $13.69 per test.

Growth in Molecular Diagnostics

There were 15 molecular tests among the top 50. Allowed charges for these 15 molecular tests soared by 76% to $903 million. Volume jumped by 69%, while the average allowed charge increased by 3.9% to $435 per test. The strong growth occurred despite the fact that nearly 50% of all molecular test claims are denied by Medicare Part B contractors (see *LE*, November 2019).

The fastest-growing test was APC gene analysis (CPT 81201). Allowed charges jumped to $30.4 million in 2018 from $1.3 million in 2017—an increase of 2,225%. APC gene testing is used for confirmation of familial adenomatous polyposis (FAP). FAP is an inherited colorectal cancer syndrome that accounts for up to 1 in 200 colorectal cancers. Among the lab companies performing a high volume of APC gene analysis was LabSolutions LLC (Atlanta, GA). The Department of Justice charged LabSolutions and its owner, Minal Patel, with soliciting medically unnecessary molecular tests from Medicare beneficiaries late last year (see *LE*, October 2019).

Another fast-growing test was Molecular pathology procedure, Level 9 (CPT 81408), which skyrocketed 1,189% to $123 million of allowed charges in 2018. Among the lab companies performing a high volume of this procedure were LabSolutions and National Premier Laboratories (Stockbridge, GA), which specializes in both toxicology and molecular testing.

The Rise of Proprietary Branded Molecular Tests

Among the 15 molecular tests were six proprietary tests, including Exact Sciences' Cologuard and OncotypeDX tests, Myriad Genetics' Vectra DA test, Roche's FoundationOne CDx, CardioDx's Corus CAD test and Veracyte's Afirma Thyroid FNA Analysis.

Subdued Drug Test Spending

Allowed charges for five drug testing codes increased by only 0.6% to $911 million. Volume was up 3%, while average allowed charge fell by 2.4% to $133 per drug test panel. Increased payer scrutiny and lower reimbursement for drug test panels appear to have led many drug testing labs to diversify into molecular testing.

Top 50 Medicare Part B CLFS Tests by Allowed Charges for 2018

CPT	Description	2018 Allowed Charges	2018 Allowed Services	2018 Avg. Allowed Charge	1-Year % Chg. Allowed Charges	1-Year % Chg. Allowed Services	1-Year % Chg. Avg. Allowed Charge
80053	Comprehensive metabolic panel*	$376,167,159	28,874,501	$13.03	16.6%	0.0%	16.7%
G0483	Drug test defin (22+ classes)***	318,562,436	1,295,351	245.93	3.2%	3.2%	0.0%
80061	Lipid panel*	316,798,860	19,176,074	16.52	12.2%	-0.6%	12.8%
84443	Thyroid stim hormone (TSH)*	314,040,900	15,137,364	20.75	-9.7%	0.1%	-9.7%
85025	Complete CBC w/auto diff wbc*	282,848,218	29,505,908	9.59	-9.6%	-0.8%	-8.9%
82306	Vitamin D*	235,244,806	6,436,870	36.55	-8.2%	0.4%	-8.6%
80307	Presumptive drug screen***	227,961,585	3,184,332	71.59	-1.7%	3.8%	-5.3%
83036	Glycosylated hemoglobin (A1C)*	178,428,197	14,887,081	11.99	-9.0%	0.8%	-9.7%
81528	Cologuard colorectal screen**	170,684,377	335,455	508.81	43.6%	44.6%	-0.7%
G0482	Drug test defin (15-21 classes)***	160,917,347	810,681	198.50	-0.9%	0.4%	-1.3%
81479	Unlisted molecular pathology**	135,670,753	89,721	1,512.14	17.4%	20.2%	-2.3%
81408	Mopath procedure level 9**	123,156,681	62,280	1,977.47	1,189.2%	970.7%	20.4%
G0480	Drug test defin (1-7 classes)***	105,754,560	936,735	112.90	4.0%	6.0%	-1.9%
G0481	Drug test defin (8-14 classes)***	97,404,807	626,261	155.53	-3.2%	-1.4%	-1.8%
81519	OncotypeDX breast cancer test**	78,474,014	20,262	3,872.96	27.8%	13.6%	12.5%
83970	Parathormone test*	77,108,520	1,513,769	50.94	-6.3%	4.1%	-10.0%
80048	Basic metabolic panel*	74,709,698	7,163,958	10.43	2.6%	-3.2%	6.0%
82607	Vitamin B12*	74,570,038	4,007,760	18.61	-9.9%	0.0%	-10.0%
84153	Total PSA*	74,238,666	3,269,628	22.71	-8.8%	1.1%	-9.8%
84439	Assay of free thyroxine*	58,250,989	5,235,169	11.13	-7.3%	2.4%	-9.5%

CPT	Description	2018 Allowed Charges	2018 Allowed Services	2018 Avg. Allowed Charge	1-Year % Chg. Allowed Charges	1-Year % Chg. Allowed Services	1-Year % Chg. Avg. Allowed Charge
87086	Urine culture/colony count	51,404,406	5,164,095	9.95	-10.7%	-1.1%	-9.7%
81162	BRCA1&2 seq & full dup/del**	50,896,967	22,615	2,250.58	-3.0%	7.6%	-9.9%
87798	Infectious agent NOS by DNA**	50,206,286	1,165,255	43.09	93.7%	70.0%	13.9%
85610	Prothrombin time*	48,672,346	10,036,377	4.85	-21.9%	-13.5%	-9.8%
82728	Ferritin*	47,696,393	2,834,352	16.83	-6.4%	3.7%	-9.7%
87633	Respir virus detect by DNA**	41,217,268	82,733	498.20	48.6%	58.4%	-6.2%
87507	Infectious agent gastro by DNA**	41,064,234	83,947	489.17	76.2%	84.8%	-4.6%
82746	Folic acid*	39,745,408	2,190,090	18.15	-8.7%	0.7%	-9.4%
83880	BNP test*	39,699,224	948,252	41.87	-8.5%	0.5%	-9.0%
84403	Total testosterone	36,395,682	1,144,344	31.80	-7.1%	2.6%	-9.4%
81490	Vectra DA test rheum arthr**	35,117,313	41,774	840.65	30.6%	-8.2%	42.4%
0037U	FoundationOne CDx (F1CDx)**	33,396,801	9,870	3,383.67	NA	NA	NA
81317	PMS2 gene full sequence**	32,237,646	45,628	706.53	1,042.0%	1159.1%	-9.3%
86235	Nuclear antigen antibody*	31,298,915	1,426,971	21.93	-3.2%	5.6%	-8.4%
87186	Microbe susceptible MIC*	31,014,404	2,907,393	10.67	-7.6%	0.8%	-8.4%
81493	Corus CAD test**	30,576,000	29,120	1,050.00	4.0%	3.2%	0.7%
G0103	PSA screening	30,513,075	1,344,061	22.70	-9.3%	0.6%	-9.9%
81201	APC gene analysis**	30,393,020	39,045	778.41	2,224.6%	822.0%	152.1%
84481	Free T3*	29,895,606	1,430,675	20.90	-1.2%	5.6%	-6.4%
82570	Creatinine*	29,520,593	4,621,472	6.39	-7.9%	1.5%	-9.3%
81001	Urinalysis auto with scope*	28,133,218	7,180,352	3.92	-10.4%	-0.7%	-9.8%
85027	Complete CBC automated*	27,852,389	3,490,649	7.98	-8.2%	0.8%	-8.8%
81298	MSH6 gene full sequence	26,848,339	41,866	641.29	1,082.3%	432.4%	122.1%
83735	Magnesium*	26,823,017	3,244,253	8.27	-7.0%	2.9%	-9.6%
82043	Albumin*	26,330,209	3,697,152	7.12	0.7%	1.5%	-0.8%
83550	Iron binding test*	25,319,039	2,348,393	10.78	-4.5%	3.9%	-8.1%
87088	Urine bacteria culture*	23,836,493	2,389,304	9.98	-8.4%	-0.2%	-8.3%
83540	Iron assay*	23,729,249	2,972,990	7.98	-6.4%	3.2%	-9.3%
87804	Flu test with optic*	23,658,974	1,431,069	16.53	33.3%	27.4%	4.7%
81545	Afirma thyroid gene expression**	22,852,625	6,348	3,599.97	35.4%	21.1%	11.7%
	Total for 30 Routine Tests	2,683,944,691	196,010,325	13.69	-3.2%	-0.4%	-2.7%
	Total for 15 Molecular Tests	902,792,323	2,075,919	434.89	75.5%	68.9%	3.9%
	Total for 5 Toxicology Tests	910,600,736	6,853,360	132.87	0.6%	3.0%	-2.4%
	Grand Total All 50 tests	$4,497,337,750	204,939,604	$21.94	7.3%	0.1%	7.2%

*Routine test **Molecular test ***Drug test

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

Spotlight Interview with OmniPathology CEO Mohammad Kamal

OmniPathology (Pasadena, CA) was formed in 2009 with an initial focus on gastrointestinal pathology. The lab has 15 employees, five of whom are pathologists. *Laboratory Economics* recently spoke with Founder and CEO Mohammad Kamal, MD.

What areas does Omni Pathology specialize in?
When we started our main focus was GI pathology, but in 2017, we decided to expand our focus into gynecological, male and urological pathology services with our OmniPrism and OmniPathways test panels that combine morphology, immunohistochemistry and FISH testing. This approach allows us to improve the screening for cervical and anal cancers by providing additional information that the traditional approach does not offer. We go beyond the scope by looking for cytogenetic and immunophemotypic changes that identify high-risk patients. We also have FISH tests for bladder cancers and Barrett's esophagus.

What geographic areas do you serve?
We provide services to about 520 physicians in a number of states, including California, Arizona, Nevada, Texas, Florida, New Jersey and Pennsylvania.

Is the business growing?
Between 2018 and 2019, we increased our CPT test code volume by 43%. Overall, we have had over 10% growth annually since 2013. We had a bad year in 2013 because of a major Medicare reimbursement reduction for CPT code 88305. Our recovery started at the end of 2014, and 2015 was a great year. We learned to diversify more. In 2018, we expanded our lab from 1300 square feet to 7200 square feet. This year we are aiming for 40% growth as a result of our expanded services in GYN, male health and clinical trials.

Do you use digital pathology?
Yes. We use it to a limited extent in primary diagnosis. We are currently engaged in conversations and research to increase our footprint in digital pathology, as I believe it's the way of the future.

Do you have any plans to expand into other areas?
Yes. We are always looking for growth opportunities. In 2020, we have an initiative to build an infrastructure that will position OmniPathology as one of the premier clinical trial partners in the pharmaceutical and biotechnology industries. We already are working with a CRO which has made us their preferred pathology lab for two clinical trials.

In the long run, do you think there is a place for small independent pathology labs, or will large health systems and Quest and LabCorp dominate?
More important than being independent, it's important to highlight that we are a physician-owned organization. This means a lot because as physician-owned, we are always going to be compassionate. This is a major contrast to large corporations. Yes, I believe there is a place for independent pathology labs in the long run. Our healthcare system is better when we allow independent and small players to compete, which means allowing them into insurance networks.

What is your reaction to the recent Anthem BC of California rate cuts?
The Anthem BC rate cuts, in my opinion, are a form of bullying. They are arbitrary and illogical. In their cuts Anthem did not follow any guidelines and used a take-it-or-leave-it approach, knowing that the big players will take it. So it is in a way a tactic to squeeze out everyone else. Over the long run, these disruptive and draconian cuts are not good for our healthcare system and will destabilize our industry because they are disregarding quality.

What advantage does an independent pathology practice have over labs?
Before I started OmniPathology, I held leadership positions at some of the large labs. Organizations like OmniPathology have efficiencies that the larger labs don't have. We provide faster turnaround time, higher quality and better and more personalized customer service. We have a compassionate approach to billing, where we can customize payment plans for patients with financial hardship. Our customers can directly reach out to our pathologists to discuss their cases, which is very hard to do in a larger organization. Revenues are reinvested in the organization rather than being spent on overinflated executive bonuses and sales commissions. Our approach in adopting technologies is guided by a strong understanding of the test clinical utility and clinical outcomes. As a physician executive, I engage my pathology teams and seek their input in everything we do, while in larger organizations, final decisions are made by non-technical executives.

What do you see as your biggest opportunities?
Our biggest opportunity is the screening and early detection of anal cancer. We have seen recent reports addressing the increased incidents of anal cancer. We validated TERC FISH on anal pap smears and use it as a valuable tool to enhance our capability to properly screen high-risk patients. When you combine the morphology of the anal pap with HPV testing and TERC FISH, you maximize the diagnostic potential of the sample and identify patients who require more aggressive treatment and follow-up.

You also are an artist, selling abstract photographs of cells. How did you get into that?
It's a hobby. I find it's a unique way to bridge science and art. Arman Trousseau said, "Every science touches art at some points – every art has its scientific side; the worst man of science is he who is never an artist, and the worst artist is he who is never a man of sciences." I want my art to inspire scientists to encourage their inner artist and inspire artists to encourage their inner scientist.

Enzo Delays Shareholder Meeting; Harbert Files Lawsuit (*cont'd from page 1*)
Enzo says the delay is needed so that shareholders can consider a new proposal to keep President Barry Weiner on its board by increasing the size of the board from five to six directors. In addition, Enzo wants to add a seventh board seat to be filled by an independent director to be identified in the near future.

HDF says that all three leading independent proxy advisory services had recommended voting in favor of HDF's two board nominees, Fabian Blank and Peter Clemens. And that by January 28, three days before the election, with most of the expected votes cast, it was clear that both its nominees would win seats.

HDF has filed a lawsuit in Southern District of New York court against Enzo's board, alleging it has engaged in "acts of entrenchment and misuse of the corporate machinery" to keep Barry Weiner on the board after most of the company's shareholders had voted and it had become clear that Weiner would be removed.

"Recognizing that it was too far behind in votes to defeat HDF's nominees, Enzo agreed in the January 28 Enzo Press Release to no longer oppose HDF's nominees but instead would seek shareholder approval to expand the size of the board by at least one additional seat in a desperate attempt to keep Weiner on the board and reduce the influence of HDF's nominees," according to the lawsuit.

HDF says that Enzo has violated federal securities laws, and is seeking recompense for those actions which have cost hundreds of thousands of dollars in additional, unnecessary legal, proxy and other advisory fees. HDF says that its lawsuit also lays "a marker so that the director defendants' gamesmanship stops."

HDF owns 11.8% of Enzo's outstanding shares, making it the company's largest shareholder (see *LE*, January 2020).

Quest To Buy Memorial Hermann Outreach Lab (*cont'd from page 1*)
The asset purchase involves nonpatient outreach clinical lab tests and Pap tests, but does not include anatomic pathology testing services. AP services will continue to be provided by Memorial Hermann's existing contracted pathology groups, including Brown & Associates Medical Labs, Memorial Pathology Consultants and North Houston Pathology Associates.

Upon closing, expected by mid-year, MHDL's nonpatient clinical lab test volume will transition to Quest's regional lab in Houston. Other parts of the comprehensive agreement include:

- Quest will provide professional lab management services through a multi-year agreement for all of Memorial Hermann's hospital-based inpatient labs. Memorial Hermann will continue to wholly own these labs.
- Quest will be the sole preferred lab provider for the Memorial Hermann Health Plan, which covers approximately 50,000 members.
- Quest will become the primary reference testing lab for all 17 Memorial Hermann hospitals.

"As part of Memorial Hermann's commitment to lower the cost of care, the system intends to utilize Quest's expertise and scale to improve cost-efficiencies while maintaining the high quality services and comprehensive resources," according to David Callender, MD, Memorial Hermann President & CEO.

Regarding any potential layoffs, a MHHS spokesperson says that the majority of affected lab outreach employees will have the opportunity to either transition to Quest or transition to another role within Memorial Hermann.

A Quest spokesperson says that the company will operate about 80 PSCs in the greater Houston area (with the addition of MHDL) and looks forward to expanding in that region. Greater Houston (Houston-The Woodlands-Sugar Land) has approximately 7 million residents and is one of the largest and fastest growing cities in the United States.

A Brief History of Lab Outreach Testing at Memorial Hermann
Hermann Hospital, which merged with Memorial Healthcare in 1997, formed a 50-50 joint venture outreach lab with Dynacare back in 1995. Dynacare's contract to provide lab testing services to Hermann Hospital expired and was not renewed in late 2000. In addition, Dynacare acquired the remaining 50% stake in the outreach lab JV for $7 million in 2001. Dynacare was subsequently bought by LabCorp in July 2002. Memorial Hermann then re-entered the outreach lab business on its own by creating MHDL.

One of the Largest Outreach Labs in the Nation
MHDL is based at the Memorial Hermann Hospital campus in the Texas Medical Center. Based on Medicare Part B CLFS payments, MHDL ranks among the largest hospital outreach labs in the nation (see *LE*, December 2019).

An analysis of hospital cost reports and Part B CLFS payments to Memorial Hermann indicate that MHDL grew its revenue by an average of 5-10% per year between 2014 and 2017. However, MHDL's Part B CLFS payments fell by 7% to $6.7 million in 2018, largely as a result of the PAMA rate cuts. A decline of closer to 10% most likely occurred in 2019, although this Medicare Part B CLFS data is not yet available.

Overall, *Laboratory Economics* estimates that MHDL's total nonpatient outreach revenue from all payers is currently $30 million to $50 million per year.

Memorial Hermann Laboratory Department Costs

Memorial Hermann owns and operates 14 hospitals and has joint ventures with three other hospital facilities, including Memorial Hermann Surgical Hospital First Colony, Memorial Hermann Surgical Hospital Kingwood and Memorial Hermann Rehabilitation Hospital-Katy.

Overall, Memorial Hermann's fully-loaded lab department budgets total more than $165 million per year, including lab employee salaries of more than $37 million.

Quest claims that its professional lab management services agreements typically reduce hospital lab department costs by around 20% by, among other things, leveraging Quest's purchasing economies to reduce supply, reagent and equipment costs.

Top 10 Hospitals in Memorial Hermann Health System

Hospital Name	*Staffed Beds*	*Laboratory Dept. Salaries*	*Total Laboratory Dept. Cost**	*Medicare CLFS Payments*
Memorial Hermann - Texas Medical Center	1,022	$17,133,845	$66,284,821	$6,714,963
Memorial Hermann Southwest Hospital	1,376	9,886,841	52,709,591	213,604
Memorial Hermann Memorial City Medical Center	444	2,941,541	16,768,382	61,240
Memorial Hermann Northeast Hospital	255	2,594,036	10,161,529	51,802
Memorial Hermann Katy Hospital	208	1,888,360	8,175,140	39,094
Memorial Hermann Sugar Land Hospital	145	1,764,405	7,207,288	29,376
Memorial Hermann Rehabilitation Hospital - Katy	35	511,240	2,145,020	0
Memorial Hermann Orthopedic & Spine Hospital	64	565,363	1,342,984	0
TIRR Memorial Hermann	134	124,965	522,292	5,704
Memorial Hermann Surgical Hospital Kingwood	10	0	435,911	0
Totals	**3,693**	**$37,410,596**	**$165,752,958**	**$7,115,783**

*Total laboratory department cost, including hospital overhead allocations (administrative, housekeeping, cafeteria, et al.)
Source: *Laboratory Economics* from Hospital Cost Reports for 2018

Quest Buys Blueprint Genetics

Quest Diagnostics has acquired the Finnish genetic testing company Blueprint Genetics in an all-cash deal. Financial terms were not disclosed.

Blueprint, which was founded in 2012, provides 3,900 targeted single gene and over 200 panel tests for rare genetic diseases. The company's initial next-generation-sequencing technology was developed at Stanford University, which was an early investor in the startup. Blueprint has a total of roughly 150 employees, including about 30 PhD geneticists. The company operates a specimen collection and billing office in Seattle that ships patient samples to the company's CAP-accredited laboratory in Helsinki, Finland.

Blueprint's competition in the United States includes Ambry Genetics, BioReference's GeneDx, Caris Life Sciences, Invitae, Paradigm Diagnostics and PreventionGenetics.

Tommi Lehtonen, CEO and co-founder of Blueprint, will continue to lead the company as General Manager, reporting to Quest's Carrie Eglinton Manner, Senior Vice President, Advanced Diagnostics.

Quest Reports Full-Year 2019 Financial Results

Quest Diagnostics reported net income of $858 million for full-year 2019, up from $736 million in 2018. Quest's overall revenue increased by 2.6% to $7.726 billion, with acquisitions contributing more than 2% to revenue growth. Quest's average revenue per requisition decreased by 1.3% to an estimated $44.86 per req. A summary of key topics discussed by CEO Steve Rusckowski and CFO Mark Guinan on a January 30 conference call follows.

Volume Growth

Overall, Quest's gene-based and esoteric testing grew by approximately 5% to $2.5 billion in 2019. The growth drivers included drug monitoring, tuberculosis testing (QuantiFERON and T-SPOT), Hemepath, blood cancer testing and Cardio IQ cardiovascular testing, according to Rusckowski.

Immunoassay Vendor Consolidation

Siemens Healthineers has won a contract to provide up to 120 Atellica Solution immunoassay analyzers to 19 esoteric and core laboratories owned by Quest in the U.S. The Atellica system will also be installed at the new 250,000-square-foot lab that Quest is building in northern New Jersey. The consolidation to one immunoassay vendor is expected to save Quest $35 million per year.

Increased Competition for Hospital Send-Out Testing

Guinan said that hospitals are focusing more on pricing when selecting a reference lab. "In the past you might extend the [reference lab] contract with the understanding that you had a good reasonable price and they had good quality and all those kind of things. More and more of these are going to RFP where there's an opportunity for price competitors to come in and compete on price very highly."

Wage Pressure

"We have pressure in some geographies to up our wages more than we have historically because we have to be competitive with other companies," said Rusckowski. He noted that Quest employs about 12,000 phlebotomists, more than 3,500 couriers, and thousands of specimen processors. "And so, if you look at the front end of our value chain, that's where we see some pressure."

UnitedHealth's Preferred Laboratory Network

Guinan said that United was focusing on how to reduce out-of-network usage. "They've done a number of things to try to reduce that, including sharing that information with members of the PLN, where we can go out and target some of those accounts and explain to the physician why there's a benefit in steering patients to a preferred lab member."

Guinan said that United began rolling out the PLN benefit, which offers members zero-dollar out-of-pocket cost for lab tests, to its fully-insured plans in January. "And then there's the sponsored plans, which is the next step. So this is a long-term initiative that is certainly reaping some benefits. But it's not in terms of a steep change where this is going to overnight move on dramatically."

Quest Diagnostics Financial Summary ($ millions)

	2019	2018	% Chg
Total revenue	$7,726	$7,531	2.6%
Lab testing revenue	7,405	7,204	2.8%
Other revenue*	321	327	-1.8%
Operating cash flow	1,243	1,200	3.6%
Capital expenditures	400	383	4.4%
Free cash flow	843	817	3.2%
Pretax income	1,076	926	16.2%
Net income	858	736	16.6%
Diluted EPS	$6.28	$5.29	18.7%
# Employees	46,000	46,000	0.0%
Avg. revenue per employee	$167,957	$163,717	2.6%
Est'd number of requisitions	175.0	167.9	4.3%
Est'd revenue per requisition	$43.86	$44.44	-1.3%

*Other revenue includes clinical trials testing, info tech services and testing for life insurance companies

Source: Quest Diagnostics and *LE's* estimates for number of reqs and average revenue per req.

LabCorp Reports Full-Year 2019 Financial Results

LabCorp (Burlington, NC) reported net income of $823.8 million for the full-year 2019, down from $883.7 million in 2018. LabCorp's overall revenue increased by 2.0% to $11.6 billion in 2019.

Revenue from LabCorp's lab testing business decreased by 0.4% to $7 billion in full-year 2019. This year LabCorp expects its lab testing business to increase its revenue by 0.5% to 2.5%. This guidance includes a -1.3% impact from PAMA and -0.9% from UnitedHealth's nonrenewal of the BeaconLBS contract in Florida.

LabCorp expects revenue from its Covance Drug Development division to grow by 7% to 9.5% in 2020.

On February 13, LabCorp held a conference call with analysts and investors. Here are some comments on a few key topics from CEO Adam Schechter.

Impact from PAMA
Schechter said that the PAMA rate cuts reduced the company's lab testing revenue by approximately $100 million in 2019. He expects a similar $100 million revenue loss from PAMA this year and again in 2021.

UnitedHealth's Preferred Laboratory Network (PLN)
"I don't assume there'll be a significant shift [to PLN labs] in 2020 because they're rolling it out as we speak….If it works for United, I think that other organizations may see this as an opportunity to help them reduce their laboratory costs by moving over business to a lab like ours."

Hospital Lab Acquisitions
"As I look at the hospital tuck-in acquisitions, I can tell you that our list is long. There are many discussions that we're having around the country with both local and regional labs and hospitals… I believe over time it [hospital lab deals] will begin to accelerate, particularly as they feel the continued impact from PAMA."

Direct to Consumer Genetic Testing
"We saw a significant decline in 2019 versus 2018. It's now a very small amount of our total volume and of our total revenue and operating income." *Laboratory Economics* notes that LabCorp has had a contract to provide genotyping services to 23andMe Inc. (Sunnyvale, CA) since 2008. After years of strong demand for its ancestry and health testing services, 23andMe recently laid off 100 employees, or 14% of its workforce, citing a slowdown in consumer demand.

LabCorp Financial Summary ($ millions)

	2019	2018	% Chg
Total revenue	$11,554.8	$11,333.4	2.0%
LabCorp Diagnostics	6,999.9	7,030.8	-0.4%
Covance Drug Development	4,578.1	4,313.1	6.1%
Operating cash flow	1,444.7	1,305.4	10.7%
Capital expenditures	400.2	379.8	5.4%
Free cash flow	1,044.5	925.6	12.8%
Pretax income	1,104.9	1,268.3	-12.9%
Net income	823.8	883.7	-6.8%
Diluted EPS	$8.35	$8.61	-3.0%
Est'd number of requisitions	158.4	157.5	0.6%
Est'd revenue per requisition	$44.20	$44.65	-1.0%
# Lab employees	39,000	39,000	0.0%
Avg. revenue per lab employee	$179,485	$180,277	-0.4%

Source: LabCorp and *LE's* estimates for number of reqs and average revenue per req.

Non-Coverage Best Policy For Ending Unnecessary Lab Tests

Payment policy changes are more effective for reducing utilization of low-value lab tests than clinical practice recommendations, according to a study published online on February 10 in JAMA Internal Medicine.

The study (*Comparison of Payment Changes and Choosing Wisely Recommendations for Use of Low-Value Laboratory Tests*) compared the changes in the utilization of Vitamin D and trilodothyronine (T3) level testing after the release of the American Board of Internal Medicine's Choosing Wisely recommendations versus changes associated with a related coverage policy change.

Choosing Wisely is an initiative of the ABIM Foundation that seeks to educate physicians and patients on avoiding unnecessary medical tests, treatments and procedures. Choosing Wisely recommends against Vitamin D and T3 tests for population-wide screening because most patients (outside of specific high-risk groups) are unlikely to derive any benefit from this testing.

The study's lead author was James Henderson, PhD, from Consulting for Statistics, Computing & Analytics Research (CSCAR) at the University of Michigan.

Records for a total of 54 million patients from 2010 to 2015 were analyzed from three healthcare payer systems: government-funded coverage in Ontario, Canada (CA-Ontario); Veteran's Health Administration coverage to U.S. veterans (US-Veterans); and the U.S. employer-sponsored insurance market (US-Commercial).

Based on analysis from the Ontario Health Tech Advisory Committee, CA-Ontario eliminated reimbursement to labs for Vitamin D testing for average-risk individuals effective December 2010. Subsequently, there was a 93% reduction in Vitamin D tests, according to the study.

In comparison, the Choosing Wisely recommendations against Vitamin D screening were published in the United States in February 2013, but resulted in only 13.8% fewer tests for US-Veterans and 14% fewer for US-Commercial.

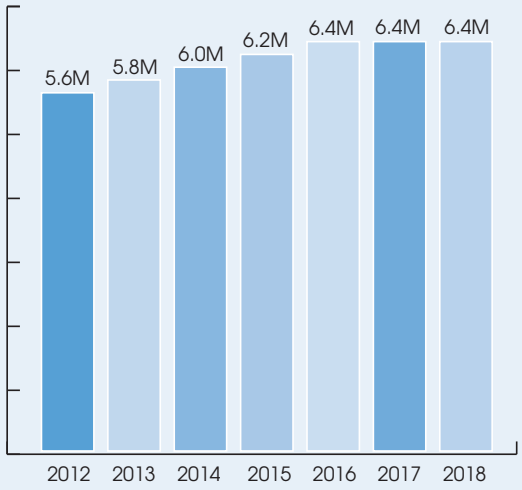
Meanwhile, recommendations against T3 testing among patients with established hypothyroidism were published in October 2013 in the United States and in October 2014 in Canada. Coverage policy was not changed for any of the three payer systems. Subsequently, there were no changes in utilization of T3 testing at either CA-Ontario or US-Veterans, while testing actually increased by 3% for US-Commercial.

"These findings suggest that recommendations alone may be insufficient to significantly reduce use of low-value services, and that pairing recommendations with policy changes may be more effective," concluded Henderson.

Medicare Vitamin D Test Volume Trends

Separately, *Laboratory Economics*' informal analysis of Medicare Part B carrier data shows that Vitamin D (CPT 82306) test volumes remain stubbornly high in spite of the Choosing Wisely recommendations. In 2012, the year before the recommendations were released, there were 6.9 million submitted claims for CPT 82306, 1.3 million denials and 5.6 million allowed claims. Fast forward to 2018 and there were 7.8 million submitted claims, 1.4 million denials and 6.4 million allowed claims.

Medicare Allowed Tests for Vitamin D



Source: *Laboratory Economics* from Medicare Part B Carrier National Summary Data, 2012-2018

Lab Stocks Up 10% So Far In 2020

Nineteen lab stocks have risen by an unweighted average of 10% so far in 2020. In comparison, the S&P 500 Index had a year-to-date total return of 4.6%. The top-performing lab stocks thus far in 2020 have been Interpace Biosciences, up 76%; Invitae, up 68%; and CareDx, up 24%. Shares of LabCorp are up 15% and Quest Diagnostics is up 6%.

Company (ticker)	Stock Price 2/14/20	Stock Price 12/31/19	2020 Price Change	Enterprise Value ($ millions)	Revenue (Latest 12 mos.)	Enterp. Value/ Revenue
LabCorp (LH)	$195.28	$169.17	15%	$25,750	$11,555	2.2
Quest Diagnostics (DGX)	112.85	106.79	6%	19,180	7,726	2.5
Sonic Healthcare (SHL.AX)	31.63	28.75	10%	17,190	6,130	2.8
Exact Sciences (EXAS)	98.18	92.48	6%	13,880	876	15.8
Guardant Health (GH)	84.30	78.14	8%	7,300	184	39.6
NeoGenomics (NEO)	34.18	29.25	17%	3,210	378	8.5
Natera (NTRA)	35.64	33.69	6%	2,680	286	9.4
Invitae (NVTA)	27.04	16.13	68%	2,460	196	12.6
Myriad Genetics (MYGN)	19.42	27.23	-29%	1,600	813	2.0
Opko Health (OPK)	1.57	1.47	7%	1,290	899	1.4
Veracyte (VCYT)	26.85	27.92	-4%	1,130	116	9.7
CareDx (CDNA)	26.67	21.57	24%	1,090	115	9.5
Castle Biosciences (CSTL)	31.80	34.37	-7%	473	46	10.4
Exagen (XGN)	21.06	25.40	-17%	185	40	4.7
DermTech Inc. (DMTK)	13.90	12.40	12%	140	2	58.1
Enzo Biochem (ENZ)	2.22	2.63	-16%	78	80	1.0
Interpace Biosciences (IDXG)	8.80	5.00	76%	58	26	2.2
Psychemedics (PMD)	9.25	9.15	1%	48	38	1.3
Biocept (BIOC)	0.32	0.29	12%	4	5	0.9
Unweighted Averages			10%	$97,746	$29,512	3.3

Source: *Laboratory Economics* and Capital IQ

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