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HIGHLIGHTS

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DX Earnings Report: PAMA Cuts Make Little Dent on Q1 Lab Earnings

One quarter into its existence, the new PAMA Medicare Part B fee schedule seems to be having only a marginal impact on at least publicly traded labs. In fact, the recently published Q1 earnings reports suggest that the 2018 fiscal year is off to a very strong start. The two salient trends revealed by the reports:

1. Atypically high revenue growth among firms that have recently completed significant acquisitions (including Abbott, Becton Dickinson, PerkinElmer, Quidel and Thermo Fisher Scientific); AND
2. Continued strength in core lab products and services.

The intense flu season was another key factor of success in the first quarter, lifting firms that offer respiratory and influenza products, e.g., BioMérieux, Danaher, GenMark Diagnostics and Meridian Bioscience, but harming just about everybody else by keeping would-be patients home. The terrible weather of January, February, and March also exercised a negative impact on most.

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Market Trends: Genetic Testing Becoming a Hot New Employee Benefit

While its clinical utility remains subject to debate, genetic testing has proven its value as an employment recruitment tool, especially on the West Coast where technology firms are leveraging its allure as an employee benefit to compete for talent in a tight job market.

Employees Want Genetic Testing as a Health Benefit

Scientific concerns over genetic testing's effectiveness in screening healthy populations for rare mutations are well documented. But this seems not to have discouraged interest in offering such tests as an employee health benefit. Companies promote genetic testing as a means to personalize health care through develop-

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Gainers

Continuing recent trends, gainers outnumbered decliners by nearly 7:1 with 34 of 40 companies reporting higher Q1 revenues versus the same period in 2017. Only five reported declines (and one firm, Oxford Immunotec, was flat). Gains were not only widespread but significant. Thus, among the gainers, only three failed to make their Wall Street targets:

- Quest Diagnostics which posted 3% growth but came up just $2 million shy of its $1.90 billion target;
- NantHealth which missed its $23.3 million target by $1 million despite 17% growth; and
- Struggling Waters whose $498 million in Q1 revenues were up 7% year over year but nowhere close to the $535.3 million target.

Fueled by better than expected earnings, no fewer than eight firms raised their 2018 revenues and/or Earnings Per Share guidance during the quarter. And missing its earnings target by over $37 million didn't prevent Waters from defiantly doing the same.

Decliners

Despite the dire predictions of PAMA's impact on revenues, only five labs posted revenue declines in Q1. But most of the declines were modest, explainable and/or accompanied by better long-term news, including:

- Fluidigm: -1% due to slow mass cytometry spec sales;
- Myriad Genetics: -2% caused by a 3% decrease in molecular diagnostics that was partially offset by 91% growth in Prolaris prostate cancer test sales, leading the firm to upwardly adjust its revenues and EPS guidance for the year;
- Opko Health: -4%, where PAMA cuts took their toll but still didn't keep the company from crushing its revenue targets ($254.9 million earned versus $236.9 million estimated); and
- Siemens Healthineers: -5% due in large part to foreign currency effects and growing pains from its recent spinout and IPO.

The one exception to the silver-linings list is Pacific Biosciences which continues to spiral downward with a 22% falloff in Q1 revenues. Wall Street was expecting a loss; but the San Francisco-based firm's $19.4 million in revenues fell woefully short of the $24.5 million average analyst estimate.

The Billion-Dollar Labs

Of the billion-dollar labs, only Quest Diagnostics missed its Wall Street target. But the miss was narrow and belied by the positive growth of 3% despite PAMA cuts that were estimated to impact 12% of its business. The predominant theme among the other giants was massive growth swollen by revenues from recent acquisitions but backed up by rock solid performance in core sectors, including:

- Abbott, where Alere and St. Jude revenues fueled 17% reported growth but which also achieved 7% organic growth;

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- Thermo Fisher Scientific where the absorption of Pantheon lifted reported revenues 23% but organic revenues also grew 6%, leading the firm to raise its 2018 guidance; which followed a spectacular Q3 with an even more impressive fourth quarter featuring 22% growth at $6.05 billion, (versus the Wall Street target of $5.7 billion) and ending the year with 14% growth at $20.92 billion;
- PerkinElmer—25% reported growth, including Euroimmun, 6% organic growth;
- Becton Dickinson—42% reported growth, including CR Bard, 5% organic growth; and
- LabCorp—18% growth, 8% organic growth excluding acquisitions revenues.

Diagnostics Earning Reports 1Q 2018
(At least $10 million in sales)

COMPANY	QUARTERLY REVENUES			DIAGNOSTICS SEGMENT PERFORMANCE
	Total 1Q 2018	YOY	Wall Street Estimate	
Abbott Laboratories	$7.39 billion	+17%	$7.29 billion	Organic growth not counting Alere and St. Jude purchases of 7%; DX sales of $1.84 billion v. $1.16 billion 1Q 2017 lifted by strong flu season
Agilent Technologies	$1.21 billion	+9%	$1.21 billion	DX and genomics up 9% to $219 million, crosslab group up 13% to $426 million, life sciences up 7% to $561 million
Becton Dickinson	$4.22 billion	+42%	$4.12 billion	Up 5% on a comparable, currency-neutral basis excluding CR Bard acquisition; DX systems revenues up 17% to $410 million; raises guidance to 31 to 31.5% revenue growth (versus 30 to 31% growth)
BioMérieux	$726.6 million	+3%	NA	Microbiology, molecular biology and immunoassays up 4% driven by intense flu season and strong Asia Pacific sales
Bio-Rad	$551.5 million	+10%	$527.2 million	Clinical diagnostics up 9% to $350.8 million driven immunology, diabetes and quality control products
Bio-Techne	$164 million	+14%	$164 million	Diagnostics revenue up 10% to $28.5 million
Bruker	$431.7 million	+12%	$417.4 million	Organic growth of 4% net of 1% in acquisition boosts and 8% in positive currency effects
CareDx	$14.1 million	+21%	$13.3 million	Stellar performance driven by launch of Allosure kidney transplant test which drove 34% spike in diagnostics revenues
Danaher	$4.70 billion	+12%	$4.54 billion	Currency lent 5% boost and acquisitions another 1%; intense flu season drove huge growth in Cepheid core revenues
Exact Sciences	$90.3 million	+87%	$86.9 million	Company continues to ride success of Cologuard with test volume of 186,000; would have been even higher but for flu season which kept people home
Fluidigm	$25.2 million	-1%	NA	30% decline in instruments (especially in mass cytometry) revenue to $7.5 million offsets 23% increase in consumables to $13 million
Foundation Medicine	$52.8 million	+101%	$44.9 million	Clinical testing up 62% to $18.8 million; 2Q revenues likely to get lift from recent CMS approval of FoundationOne CDx test as ADLT
GenMark Diagnostics	$20.6 million	+65%	$17.1 million	Intense flu season drives growth in respiratory testing and new sales of ePlex analyzers
Genomic Health	$92.6 million	+13%	$89 million	New prostate cancer test revenues up 75% to $5.8 million and Oncotype DX breast cancer revenue up 4%
Hologic	$789.3 million	+10%	$781.8 million	Solid overall growth despite 6% decline in diagnostics to $297 million as a result of bad weather and severe flu season

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COMPANY	QUARTERLY REVENUES			DIAGNOSTICS SEGMENT PERFORMANCE
	Total 1Q 2018	YOY	Wall Street Estimate	
Illumina	$782 million	+31%	$743.5 million	NovaSeq continue to drive growth in sequencing instrument revenues ($112 million, up 18%); consumables up 26% to $87 million; increases 2018 guidance to 15-16% growth and $4.45-$4.55 EPS
Invitae	$27.7 million	+169%	$26.9 million	Test volume across all areas up 150% to 64,000 samples, 59,000 of which were billable, with most of growth coming in March—Jan. and Feb. actually slow; increases 2018 revenue guidance from $120 to $130 million
Laboratory Corp. of America	$2.85 billion	+18%	$2.85 billion	DX revenues up 8% to $1.77 billion with acquisitions revenues offsetting PAMA price cuts, which company estimated cost $70 million for quarter
Luminex	$82.7 million	+6%	$80.5 million	Assay revenues up 23% to $45.8 million; molecular DX up nearly 50% led by sample-to-answer products
MDxHealth	$9.7 million	+50%	NA	55% increase in test volume; ConfirmMDx and SelectMDx prostate cancer tests up 60% to $7.9 million; totals include license fee payment of $550,000
Meridian Bioscience	$56.5 million	+4%	$55.0 million	DX revenues up 5% to $39.8 million driven by intense flu season and double-digit growth in Magellan LeadCare testing products; increases 2018 guidance to $209-$214 million (from $207-$212 million) and $.69-$.72 EPS (from $.65-$.68)
Myriad Genetics	$193.5 million	-2%	$188.2 million	Molecular test revenues down 3% to $179.7 million led by 12% losses in hereditary cancer testing sales to $123.3 million but Prolaris prostate cancer test revenues grew 91% to $6.5 million; increases 2018 guidance to $771-$713 million (from $760-$770 million) and $1.19-$1.21 EPS (from $1.11-$1.16)
NanoString Technologies	$23.1 million	+28%	$21.6 million	Consumables up 15% to $11.5 million driven by over 50% growth in Prosigna IVD kit sales to $2.2 million
NantHealth	$22.3 million	+17%	$23.3 million	Firm in process of restructuring narrows net loss from $41.1 million to $22.2 million
Natera	$62.3 million	+26%	$55.1 million	Growth driven by prenatal Panorama test ($33.3 million) and Horizon carrier screening test ($18.3 million) + $5 million NGS agreement with Qiagen
NeoGenomics	$63.4 million	+10%	$61.2 million	Growth driven by 15% increase in genetic testing volume to 178,794; molecular testing up more than 30%, double-digit growth for both flow cytometry and FISH testing; average revenue per test down 3% to $319 per test due to PAMA cuts
Opko Health	$254.9 million	-4%	$236.9 million	Decline due to PAMA cuts and 3% drop in BioReference Laboratories volume which was partially offset by double-digit increases in genetic test volume
OraSure Technologies	$42.0 million	+29%	$40.6 million	OraQuick HIV testing products up 34% to $10.7 million; OraQuick HCV testing products down 62% to $2.3 million (due to non-renewal of foreign govt. contract); molecular collection systems up 72% to $18.4 million
Oxford Immunotec	$21.4 million	--	$21.0 million	Flat growth anticipated and due largely to decline in immigrant screening test volume
Pacific Biosciences	$19.4 million	-22%	$24.5 million	Sales down 23%; instruments sharply down but consumables grew 5% to $9.1 million
PerkinElmer	$644.0 million	+25%	$619.6 million	Organic growth, not counting Euroimmun revenues, of 6%; DX revenues up 62% to $247.5 million; reduces 2018 EPS guidance from $2.28 to $2.25 but increases adjusted EPS guidance from $3.50 to $3.60
Qiagen	$343.6 million	+12%	$339.1 million	Molecular DX up 9% to $161 million, just below 50% of total sales, led by QuantiFeron latent TB test which is expected to generate $300 million in 2018 sales
Quest Diagnostics	$1.88 billion	+3%	$1.90 billion	Overall growth despite PAMA cuts, which affect 12% of business and which Quest is planning to offset via $180 million in tax savings
Quidel	$169.1 million	+150%	$150.9 million	Numbers boosted by $68.4 million in revenues from newly acquired Triage and BNP; rapid immunoassay products up 40% to $80.7 million fueled by 131% growth in Sofia products which offset 34% decline in QuickVue sales; molecular DX up 65% to $5.1 million driven by 178% in Solana sales
Roche	$13.85 billion	+5%	NA	DX up 5% driven by centralized point of care solutions and success of new Cobas t 511 and t 711, molecular diagnostics (up 6%) and blood and HPV screening (up 20%); growth in Asia expected to offset PAMA losses in US

COMPANY	QUARTERLY REVENUES			DIAGNOSTICS SEGMENT PERFORMANCE
	Total 1Q 2018	YOY	Wall Street Estimate	
Siemens Healthineers	$3.77 billion	-5%	NA	Currency effects reduced revenues 9%; DX revenues down 8% to $1.13 billion
Thermo Fisher Scientific	$5.85 billion	+23%	$5.63 billion	Lab revenues up 42% to $2.41 billion including Patheon revenues, with organic growth of 6% excluding Patheon; increases 2018 guidance to revenues of $23.62-$23.86 billion and EPS of $10.80-$10.96 EPS
Trinity Biotech	$23.8 million	+1%	NA	6% decline in point-of-care ($3.8 million) offset by 3% growth in lab revenues ($20.0 million) driven by higher diabetes and autoimmunity sales
Veracyte	$20.0 million	+22%	$18.0 million	Genomic test volume up 18% (6,864 tests, including 6,649 Affirma + 215 Percepta) driven by Veracyte's gaining of in-network with Anthem; increases 2018 revenues guidance to $83-$86 million (versus $81-$83 million)
Waters	$498.0 million	+7%	$535.3 million	Weak sales in mass spec and branded instruments; Waters calls soft quarter result of "lumpiness" and raises 2018 EPS guidance from $8-$8.25 to $8.10-$8.30

* **Bold face:** Companies that met or exceeded Q1 Wall Street revenues targets
* *Italics:* Companies that missed Wall Street revenues targets

The Dx Pipeline: A Roundup of the Month's Key New Product Launches

Agilent, Bio-Techne and Mission Bio were among the producers launching multiple products. Here's a rundown of the key diagnostic product launches from mid-April to mid-May:

NEWLY LAUNCHED PRODUCTS & SERVICES

Company(ies)	Product(s)
Agilent Technologies	EBER RNA CISH, Kappa and Lambda mRNA CISH in situ hybridization probes
Agilent Technologies	Manual IQFISH panel for lymphoma
Bio-Techne	RNAscope VS Duplex kit
Bio-Techne	RNAScope VS Universal HRP and AP assays
Bio-Techne	Updated versions of RNAscope 2.5 VS Reagent Kit-BROWN and -RED assays
Veracyte	Afirma Xpression Atlas thyroid cancer assay
Thermo Fisher Scientific	Oncomine Childhood Cancer Research Assay, NGS panel targeting mutations associated with pediatric and young adult cancers
Mission Bio	Updated Tapestri single-cell DNA analysis platform, now compatible with Illumina HiSeq 2500 sequencer, to allow for multiplexing and larger panels
Mission Bio	Tapestri Single-Cell DNA Myeloid Panel assay targeting single-nucleotide variants and indels in 47 genes
Mission Bio	Tapestri Single-Cell Tumor Hotspot Panel targeting SNV and indel hotspot mutations across 50 genes
Precipio	Two new research-use only ICEme kits for detection of mutations in KRAS Exons 2 and 3 in pancreatic cancer
DDN Storage + Parabricks	DDN high-performance Parallel Flash Data Platforms and Parabricks DNA Bricks application, jointly integrated technology platform accelerating human genome analysis
Bluebee	Bluebase assay to run on Bluebee core data analysis platform
InvivoScribe Technologies	LymphoTrack Dx TRB Assay for the Illumina MiSeq platform
Interpace Diagnostics	ThyGenNext, mutational panel for indeterminate thyorid nodules

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Diagnostic Deals: A roundup of the key mergers, acquisitions, alliances, licenses and other strategic transactions from the past month

The pace of deal making has picked up a bit, but deal volume remains relatively low on both the M&A and strategic alliance fronts. As usual, smaller molecular and genomics firms are supplying most of the energy; but after a frenetic 2017, the bigger players have toned it down. Here is an overview of the deals that did come down from mid-April to mid-May.

M&A

One of the biggest stories in 2018 lab M&A continues to be who is **not** partaking—namely, heavy hitters like Abbott, PerkinElmer and Thermo Fisher Scientific who are still digesting major acquisitions from the previous year—although the latter did make a move by acquiring DNA testing tech firm IntegenX for $65 million in March.

Agilent Technologies may be the most active firm of 2018 so far. In March, the lab instruments manufacturer announced that it had agreed to acquire privately held Advanced Analytical Technologies for $250 million. This month, it closed two more deals, including acquisitions of:

- NGS technology firm Lasergen for $105 million; and
- Swiss-based lab management software developer Genohm for an undisclosed price.

LabCorp's involvement in the period's biggest deal is something you'd expect; the surprise, though, is that this time the lab giant played the role of seller, announcing its agreement to sell off its Covance Food Solutions business to Eurofins Scientific for $670 million. The deal will allow the firm to focus on its core mission of improving health and lives, noted LabCorp CEO David King in a statement.

Meanwhile, Abcam announced that it was pulling back its takeover bid for Horizon Discovery after Horizon's board of directors rejected Abcam's offer claiming that the $364.7 million valuation on which it was based grossly understated Horizon's actual value. Abcam says it no longer intends to make any further offers for the company.

Strategic Alliances

One deal making a big splash was LabCorp and Walgreens' agreement to expand their consumer collaboration by opening 10 new LabCorp patient service centers within Walgreens stores in Florida. Last year, the companies opened five co-branded in-store locations providing specimen collection services, four in Colorado and one in North Carolina.

The Walgreens deal was only part of LabCorp's busy month. In addition to inking the Covance sale noted above, the North Carolina-based diagnostics megafirm announced a new collaboration with The Recovery Platform designed to expand access to medication-assisted opioid recovery treatment. A week earlier, LabCorp inked a deal to become the primary reference lab for the Mount Sinai Health System, one of the largest and most prestigious health networks in the metropolitan New York City area.

Here's a summary of the key diagnostic deals from mid-April to mid-May:

MERGERS, ACQUISITIONS & ASSET SALES		
Acquiring Company	**Target(s)**	**Deal Summary**
Illumina	Edico Genome	▪ Price: Undisclosed ▪ Status: Closed ▪ Illumina to use Edico's DRAGEN platform to speed up and improve its own genomic sequencing solutions
Agilent Technologies	Lasergen	▪ Price: $105 million ▪ Status: Closed ▪ In 2016, Agilent acquired 48% of Lasergen ▪ Plan is to combine Agilent's engineering expertise with Lasergen's NGS chemistry to build entire clinical sequencing workflow ▪ Newly merged firm to be called LaserGen
Agilent Technologies	Genohm	▪ Price: Undisclosed ▪ Status: Closed ▪ Agilent to integrate Genohm's SLIMS lab information management software into its own OpenLabs products
Eurofins Scientific	Covance Food Solutions (owned by Laboratory Corporation of America)	▪ Price: $670 million cash ▪ Status: Expected to close in Q3 ▪ Divesting Covance, which posted $150 million in 2017 *pro forma* revenue, frees LabCorp to focus on its core medical business
Epistem 2	Genedrive	▪ Price: £1.9 million ($2.6 million) cash ▪ Status: Conditional sale with no closing date announced ▪ Genedrive to sell its contract research and pharmacogenomics divisions so it can focus entirely on molecular diagnostics market
Sygnis	TGR Biosciences	▪ Price: €10.1 ($12.0 million) ▪ Status: Closed ▪ Acquisition of Australian reagent manufacturer enables Sygnis to expand its immunology, genomic and proteomic product and service lines
DNA Diagnostics Center	ContraVac	▪ Price: Undisclosed ▪ Status: No closing date announced ▪ Acquisition of all assets of male reproductive health company which will be relocated from Charlottesville, VA to Fairfield, OH
LGC	BioAutomation	▪ Price: Undisclosed ▪ Status: Closed ▪ LGC acquires manufacturer of MerMade line of oligonucleotide synthesis instruments
Genoptix	Rosetta Genomics	▪ Price: $9 million in cash ▪ Status: Rosetta shareholders approve proposed merger slated to close on May 27 ▪ Nay vote of Rosetta shareholder scuttled first merger agreement between the two in Dec. 2017
Reprocell	BioServe Biotechnologies (wholly owned subsidiary of Cancer Genetics)	▪ Price: Up to $1.9 million--$1.6 million upfront and balance in 6 months depending on BioServe's post-acquisition revenues ▪ Status: No closing date announced ▪ Sale of NGS and genomics services firm based in India acquired for $1.9 million in 2014 is part of beleaguered BioServe's turnaround strategy
Precision Therapeutics (formerly Skyline Medical)	Helomics	▪ Price: Undisclosed ▪ Status: To close in May ▪ Precision to acquire remaining 75% of Helomics shares after buying a 25% equity stake in Dec. ▪ As part of deal, newly formed subsidiary of Precision called TumorGenesis will merge with Helomics
Axcel (Nordic private equity investment company)	Orion Diagnostica (owned by Orion)	▪ Price: Fixed purchase price of about €163 million ($199.3) + variable component of up to €60 million based on Axcel's return on investment ▪ Status: Expected to close in Q2 ▪ Orion Diagnostica offers point-of-care isothermal amplification-based molecular diagnostic system called GenRead
Boston Scientific	nVision Medical	▪ Price: $150 million cash upfront + up to $125 million more contingent on meeting clinical and commercial milestones ▪ Status: Closed ▪ nVision developer of FDA-cleared device for collecting cells from fallopian tubes

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	**Partner 2**	**Deal Summary**
Laboratory Corporation of America	Walgreens	▪ Objective: Expand current collaboration into Florida ▪ Dynamic: Open 10 new LabCorp patient service centers within Walgreens stores in April and May (4 in Gainesville + 2 each in Palm Beach County, Pasco Country and Orlando area) ▪ Triples total number of LabCorp-branded centers (which currently includes 4 in Denver area and 1 in Morrisville, North Carolina opened in 2017)
Laboratory Corporation of America	The Recovery Platform	▪ Objective: Expand access to medication-assisted opioid treatment across US ▪ Dynamic: LabCorp to become exclusive national lab integrated within The Recovery Platform, a monitoring tool used by primary care physicians to manage patient recovery from opioid use disorder
Laboratory Corporation of America	Mount Sinai Health System	▪ Objective: Standardize and improve inpatient lab services across Mount Sinai system ▪ Dynamic: LabCorp, which is currently Mount Sinai's primary lab services provider, to standardize test menus, equipment, supplies, logistics and processes at 7 system hospitals
BGI	Mount Sinai Hospital (Toronto)	▪ Objective: Develop diagnostic test for preterm birth ▪ Dynamic: BGI to install a BGISEQ-500 sequencing instrument at hospital's Lunenfeld-Tanenbaum Research Institute ▪ First placement of BGISEQ platform in North America
BGI	Johns Hopkins University	▪ Objective: Create genomic and immunogenomic database of pancreatic cancer and related malignancies ▪ Dynamic: Will also analyze data collected by the Pancreatic Cancer Precision Medicine Center of Excellence, focusing on biomarker discovery, validation and neoepitope prediction related to patient survival, drug response and resistance
GenomeDx	Janssen Pharmaceuticals	▪ Objective: Test GenomeDx's Decipher GRID database of cancer genomic profiles with samples from prostate cancer clinical trials run by Janssen ▪ Dynamic: GenomeDx to test samples to evaluate association of prognostic and predictive genomic signatures from Decipher GRID platform
Fujirebio	Janssen Pharmaceuticals	▪ Objective: Develop test to identify Alzheimer's patients who can benefit from Janssen's investigational oral BACE inhibitor, atabecestat ▪ Assay to run on Lumipulse instrument, a chemiluminescent enzyme immunoassay system
Siemens Healthineers	Hill-Rom	▪ Objective: Comarketing of diabetes care products ▪ Dynamic: Siemens Healthineers' products in offering include DCA Vantage Analyzer for HbA1c testing and Clinitek Status + Urine Chemistry Urine Analyzer for kidney checks; ▪ Offering to also include Hill-Rom's Welch Allyn RetinaVue Network and imaging technology for teleretinal exams
Siemens Healthineers	Hermes Pardini Group	▪ Objective: Develop clinical analysis lab in Brazil ▪ Dynamic: Initiative part of Enterprise Project expected to handle 110 million sample tubes per year ▪ Siemens Healthineers to provide "fully automated multidisciplinary solution" consisting of at least 100 analyzers, including over 50 Siemens Atellica Solution clinical chemistry and immunoassay analyzers
Foundation Medicine	Roche + Dian Diagnostics	▪ Objective: Offer Foundation's NGS tumor profiling tests in China ▪ Dynamic: Dian to be exclusive clinical sequencing partner for FoundationOne, FoundationOne Heme and FoundationAct in China ▪ Roche to keep commercial exclusivity for Foundation's molecular information products in China and work with Dian to support integration of assays into local clinical care
Thermo Fisher Scientific	Daiichi Sankyo + Takeda Pharmaceuticals	▪ Objective: Use Oncomine Dx Target Test for clinical trials and drug development ▪ Dynamic: Thermo to validate additional biomarkers and gene variants on Oncomine and retain test's global commercialization rights ▪ Thermo also responsible for filing supplemental premarket approval applications with FDA
Thermo Fisher Scientific	Leica Microsystems	▪ Objective: Develop integrated cryo-tomography workflow for life science research ▪ Dynamic: Integrate Leica light microscopes with Thermo cryo-electron microscopes
SQI Diagnostics	Microdrop	▪ Objective: Sell SQI's microarray celiac and wheat allergy, and rheumatoid arthritis tests directly to consumers ▪ Dynamic: Microdrop to license rights to tests subject to performance obligations by both parties ▪ Microdrop to also purchase 2 sqidlite testing systems
Protagen	University of California, San Francisco	▪ Objective: Develop immunotherapies for prostate cancer ▪ Dynamic: Use Protagen's SeroTag platform to predict patient response to immunotherapy treatment and monitor for adverse effects, including development of cold tumors that respond poorly to immunotherapy

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	**Partner 2**	**Deal Summary**
Invivoscribe Technologies	American University of Beirut Medical Center	▪ Objective: Create reference lab offering specialized gene panels in Middle East ▪ Dynamic: Lab would test for all hematologic diseases, including leukemia and lymphoma, standardized tests and bioinformatics tools provided by Invivoscribe's Laboratory for Personalized Molecular Medicine clinical facilities in US, Japan and Germany
Partek	Dolomite Bio	▪ Objective: Develop single-cell analysis pipeline on Partek Flow software platform ▪ Dynamic: Leverage data created by Dolomite's Nadia technology for single-cell RNA sequencing to help researchers understand genomic expression patterns of single cells
Abcam	Shuwen Biotech	▪ Objective: Develop and commercialization companion diagnostics ▪ Dynamic: Abcam to provide reproducible, highly specific recombinant antibodies against key targets, which Shuwen will incorporate into CDx kits
HTG Molecular Diagnostics	Firalis	▪ Objective: Commercialization of BIOPRED, Firalis's NGS-based rheumatoid arthritis theranostic assay ▪ Dynamic: HTG to supply assay components to Firalis ▪ Firalis to manufacture, get regulatory approvals for, and sell BIOPRED assay as kits ▪ Kits to be automated on EdgeSeq systems that end users buy directly from HTG
OnRamp Bioinformatics	Advaita BioInformatics	▪ Objective: Combine respective technologies to create end-to-end genomic data analysis solution ▪ Dynamic: OnRamp's Rosalind genomic data analysis platform to be combined with Advaita's iPathway-Guide pathway analysis platform ▪ Five Prime to use to select patients for Phase 3 of its registrational FIGHT trial evaluating bemarituzumab in combination with chemotherapy as front-line treatment in patients with advanced gastric or gastro-esophageal junction cancer with FGFR2 amplification
NanoString Technologies	5 different contract research organizations including Covance, Cancer Genetics, Core Diagnostics, Propath UK and another undisclosed CRO	▪ Objective: Expand access to NanoString's Digital Spatial Profiling technology ▪ Dynamic: CROs to CROS to market DSP services to their customers via technology access program in advance of NanoString's expected 2019 commercial launch of DSP instrument platform
Invitae	Biogen	▪ Objective: Provide free genetic testing to patients diagnosed with or suspected of having spinal muscular atrophy (SMA) ▪ Dynamic: Program called SMA Identified
NimaGen	Radboud University Medical Center	▪ Objective: Develop target enrichment library prep kits for NGS ▪ Dynamic: Kits to be based on single-molecule molecular inversion probes ▪ NimaGen to manufacture kits which will be sold under its proprietary EasySeq technology line
Xifin	PriorAuthNow	▪ Objective: Integrate respective platforms to streamline diagnostic labs prior authorization process ▪ Dynamic: Combine PriorAuthNow's platform with Xifin RPM 9's intelligent automation ▪ Appalachian to also gain access to LabCorp Diagnostics' info technology and data analytics services to improve patient care
Chembio Diagnostics	LumiraDx	▪ Objective: Develop point-of-care diagnostic tests for infectious diseases ▪ Dynamic: Chembio to get LumiraDx funding if it meets specific milestones ▪ If tests get regulatory approval and are commercialized, Chembio to be paid royalty payments and sell reagents to LumiraDx
Freenome	Biognosys	▪ Objective: Improve early cancer detection and precision oncology ▪ Dynamic: Freenome to use Biognosys' technology to add protein quantification for the development of its first commercially available screening test

DISTRIBUTION, SALES & MARKETING AGREEMENTS		
Property Owner	**Distributor**	**Deal Summary**
IncellDx	BPI	▪ Products: IncellDx's OncoTect, HPV E6/E7 and mRNA tests, and IncellPrep prep kit ▪ Territories: Middle East, North Africa
VolitionRx	Active Motif	▪ Products: Research-use-only kits based on VolitionRx's Nucleosomics technology ▪ Territory: Global
Illumina	CareDx	▪ Products: Illumina's TruSight HLA v1 and v2 product lines and associated Assign HLA software ▪ Territory: Global ▪ CareDx named exclusive worldwide distributor

DISTRIBUTION, SALES & MARKETING AGREEMENTS		
Property Owner	**Distributor**	**Deal Summary**
PlexBio	Eurclone Diagnostica	▪ Products: PlexBio's IntelliPlex 1000 πCode Processor, the PlexBio 100 Fluorescent Analyzer, and several PlexBio molecular diagnostics kits ▪ Territory: Italy ▪ Exclusive
Mologic	Medisur + Peripal	▪ Products: Mologic's Periplex point-of-care test for detecting infections in peritoneal dialysis patients ▪ Territories: France, Germany, Italy, Netherlands, Austria, Switzerland
Molecular Biology Systems	Canon BioMedical	▪ Products: MBS's NextGenPCR thermal cycler instrument and consumables ▪ Territories: US, Canada ▪ Exclusive
SpeeDx	Serosep	▪ Products: SpeeDx's multiplexed PlexPCR and ResistancePlus tests ▪ Territories: UK, Ireland
Omega Diagnostics	Immunodiagnostic Systems	▪ Products: Omega's Allersys, panel of 51 allergy assays ▪ Territory: Global
LICENSES		
Licensor	**Licensee**	**Deal Summary**
Case Western Reserve University	PavMed	▪ Property: Case Western's EsoCheck technology ▪ PAVMed's newly formed sub, Lucid Diagnostics, get exclusive global rights to develop and commercialize EsoCheck cell sampling device and DNA biomarker test and all derivatives ▪ Case Western and its faculty inventors get non-cash license fee in form of minority equity stake in Lucid Diagnostics, with PavMed keeping an 82% equity interest
ERS Genomics	Evotec	▪ Property: CRISPR-Cas9 technology ▪ License enables Evotec to expand its service offering in gene-editing space
University of Nebraska	Taconic Biosciences	▪ Property: Easi-CRISPR genome-editing technology ▪ Worldwide, non-exclusive ▪ Taconic gets right to generate and sell rodent models using Easi-CRISPR technology
SUPPLY, SERVICE & TESTING AGREEMENTS		
Supplier/Servicer	**Client**	**Deal Summary**
Abbott	Sanquin	▪ Multiyear contract to supply primary serological equipment and consumables, including Abbott's Alinity s system for blood and plasma screening

Market Trends: Genetic Testing Becoming a Hot New Employee Benefit, *from page 1*

ment of a custom prevention strategy and early detection. Employers believe in the value of genetic testing in lowering their own health care costs over time.

A new survey conducted on behalf of Wamberg Genomic Advisors documents the popularity of genetic testing among employees, with two-thirds of respondents saying they would be interested if their employer offered "easy and affordable" genetic testing and shared testing results only with the employee and his/her doctor. The survey of 536 U.S. consumers from ages 26 to 64 with employer-sponsored health insurance was conducted in the fall of 2017 also found that one-quarter of employees want genetic testing only if it is free, and 9% have no interest in employer-offered genetic testing at all.

Test Makers Cash In

Of course, none of this has been lost on the lab industry. One notable example is Color (San Francisco), which built its initial business through offering low-cost physician-ordered genetic testing for hereditary cancer risk, and has now become a major player in the employee genetic screening market. The company's platform enables employees of companies like Snapchat, Visa, and Salesforce to confidentially access information about their genetic risk for common hereditary cancers and inherited heart conditions in consultation with Color's genetic counselors. Ongoing follow-up includes reanalysis in light of changes to guidelines, risk information or variant classification. Additionally, Color provides the client employer a monthly aggregated, de-identified analysis of employee participation.

Privacy & Other Concerns

Of course, genetic testing as an employment benefit and other consumer uses raises red flags, including concerns about:

- Privacy protection and the downstream health care utilization as a result of genetic tests;
- The risk that genetic test results will lead to a false sense of security and cause healthy people with average disease risk will to forgo recommended screening tests like colonoscopies;
- The converse risk that concerns over the results of genetic tests for rare genetic conditions could lead people to undergo unnecessary medical procedures.

Genome Medical Enters Employer Market

Color is not the only genetic test maker trying to make hay in the employee wellness space. Another key player is Genome Medical, a nationwide genomics medical practice made up on genetic counselors and medical geneticists, that offers a range of employee wellness benefit-related services such answering employee questions, optimizing genetic test ordering and providing second opinions. The company says it provides employees "independent, confidential access" to genetic experts via its telehealth platform and offers services for preventive health screening, cancer genetics, carrier screening, cardiovascular genetics, as well as pediatric genetics. Genome Medical says genomics companies are interested in offering the benefit to employees, with Illumina, Counsyl and Invitae among its clients.

The Dx Pipeline: A Roundup of the Month's Key New Product Launches, *from page 5*

NEWLY LAUNCHED PRODUCTS & SERVICES, *Cont'd.*

Company(ies)	Product(s)
Oxford Nanopore Technologies	Updated version of its MinKnow software
Karius	Quantitative version of its NGS-based test for identifying microbial cell-free DNA in blood
Intermountain Precision Genomics Core Laboratory	Expansion of its RxMatch Comprehensive Panel expanded 36 gene targets to 97
Bio-Rad Laboratories	Bio-Plex Pro Human Cytokine Screening Panel, multiplex assay to identify and quantify 48 analytes linked to heart disease, autoimmunity and allergy and cancer
Predicine	PredicineATLAS, liquid biopsy panel covering 600 genes and offering a readout of patients' tumor mutational burden to inform immuno-oncology treatment decisions
HiberGene	HG Pneumo/Meningo Combo test for rapid detection of meningococcal and pneumococcal meningitis
Swift Biosciences	Suite of nine tumor-specific gene panels using firm's Accel-Amplicon technology
Fast Track Diagnostics	Fast Track Cycler molecular testing platform and complementary FastFinder software
Cytena	C.sight, F.sight, and B.sight, three new single-cell printers, under its X.sight line of instruments
Qiagen	European launch of QiaSTat-Dx platform
Horizon Discovery	Edit-R CRISPR arrayed crRNA (CRISPR RNA) libraries
True Health	PlanTrue genetic carrier screening test