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HIGHLIGHTS

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DX Earnings Report: Lab Market Consolidates but Survivors Stay Strong

PAMA and private payor rate cuts and increased market competitiveness are fueling consolidation and driving smaller, independent labs (other than specialty labs) into near extinction. But the big, established companies continue to chug along, not only via acquisition revenues but organically—albeit at slightly lower year-over-year rates. Meanwhile, many of the genetic and molecular testing firms are making significant strides despite the current softness in the consumer market. Here's an overview of the key trends from FY 2019 Q3.

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Diagnostic Deals: The Fate of Illumina-PacBio Merger Hangs in the Balance

Will they or won't they? The suspense continues over whether Illumina's proposed rescue of Pacific Biosciences will actually close. The $1.2 billion cash merger, which was originally expected to close in mid-2019, is now on indefinite hold due to regulatory antitrust concerns. After promising to make a ruling by Dec. 11, the UK Competition and Markets Authority (CMA) has now expanded and extended its review until Feb. 5, 2020.

The move follows an attempt by Illumina to rescue the deal by proposing to offer perpetual, royalty-free licenses to PacBio patents to competitors in the sequencing market. But one of those competitors, Oxford Nanopore Technologies, was less than impressed with what it described as an "illusory offer which does little to offset the anticompetitive effects of the proposed merger either in the UK, or on a worldwide basis." Whether CMA agrees remains to be seen. Meanwhile,

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DX Earnings Report: , *from page 1*

Gainers

Continuing recent patterns, the vast majority of companies reported at least some revenue growth during the period (37 v. 6). Not surprisingly, the emerging genetic and molecular firms are posting the most dramatic quarterly growth rates. It's also not surprising that the vast majority of these firms have yet to become profitable. Thus, of the 15 firms that reported double-digit revenue growth for the quarter, all but 3 had negative earnings per share (EPS). The exceptions:

- Genomic Health, which reported 11% growth and positive net EPS of $0.48;
- NeoGenomics with 51% top-line growth and adjusted EPS of $0.07; and
- Castle Biosciences, which cracked the quarterly $10+ million revenues line for the first time with 300% growth and a surprising positive adjusted EPS of $0.05 (smashing the average Wall Street estimate of -$0.30 per share).

Earnings v. Expectations

Of the 37 companies that had clear consensus Wall Street estimates for Q3, 28 met or exceeded their target, including LabCorp which broke its two-quarter losing streak. For the second quarter in a row, Abbott was among the firms to fall short. Three companies had extremely disappointing third quarters:

- Qiagen, which was expecting earnings of between 4% and 5%, had to settle for 1% top-line growth due to what the company described as "significantly weaker-than-expected developments in China;" after the disappointing earnings news, the company announced the departure of its long-time CEO and a strategic pivot by partnering with former competitor Illumina for NGS kit development;
- Myriad Genetics, which posted a 9% revenue decline of $186.3 million, well below the Wall Street expectation of $202.1 million; and
- Fluidigm, which surprised the Street by coming in $2.3 million shy of its $28.7 million target thanks to a 9% decline caused by weakness in mass cytometry sales.
- Other companies that fell short of revenue targets included Bio-Rad, PerkinElmer, Luminex, PacBio and Waters.

Among the 28 companies to hit their top-line targets, three missed on the bottom line, including (in order of miss magnitude) Invitae (actual EPS of -$0.69 vs. expected EPS of -$0.56), NanoString Technologies (-$0.64 vs. -$0.54), and GenMark Diagnostics (-$0.20 vs. -$0.19).

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FY Q3's Biggest Winners

While most came out ahead, five firms had a particularly stellar quarter:

- Bruker, which posted 12% growth and $521.1 million in earnings, easily smashing its Wall Street estimate of $496.7 million thanks to strong sales in mass spectrometry solutions and microbiology;
- ExactSciences, which continues to ride Cologuard and now adds OncotypeDX to its potent genetic screening cancer product mix via the recently completely acquisition of Genomic Health;
- Guardant Health, which benefited from the powerful combination of higher test volume and revenues per test to post $60.8 million, surprising Wall Street analysts that were expecting earnings in the range of $45.4 million;
- Natera, which had what its CEO described as a "transitional quarter," by posting revenues of $77.9 million (as opposed to $74.0 million expected), nearly 20% growth, driven by higher sales of its Panorama noninvasive prenatal and Horizon carrier screening tests; and
- NeoGenomics, which posted $104.7 million, surpassing average estimates of $99.1 as a result of a 35% increase in test volume and 15% increase in average revenue per test.

Diagnostics Earning Reports for Q3 (period ended Sept. 30, 2019)

(At least $10 million in sales)

COMPANY	FY 2019 Q3			DX Segment Performance
	Total Revenue (vs. Wall Street)	YOY Revenues	EPS (vs. Wall Street)	
Abbott Laboratories	$8.08 billion ($8.10 billion)	+5% (8% on organic basis)	Adjusted +$0.84 (+$0.84)	Core lab revenues up 8% to $1.18 billion, molecular down 8% to $111 million, POC up 6% to $144 million, rapid diagnostics down -1% to $477 million
Agilent Technologies (FY Q4)	$1.37 billion ($1.33 billion)	+6%	Adjusted +$.89 (+$.85)	Diagnostics and genomics group (DGG) up $13 million to $269 million driven by pathology, companion diagnostics + pharma demand for oligo manufacturing
Adaptive Biotech*	$26.1 million ($22.1 million)	+52%	Net -$.11 (-$.24)	Sequencing, including clonoSeq testing, up 38% to $11.7 million; biopharma partnership up 65% to $14.4 million. Company went public in June 2019
Becton Dickinson (FY Q4)	$4.58 billion ($4.56 billion)	+4%	Adjusted +$3.31 (+$3.30)	DX systems up 7% to $409 million. Strong molecular sales including double-digit growth in BD Max platform and ID-AST microbiology solutions
Bio-Mérieux	$727.2 million	+13%, 10% organic	Not reported	Molecular biology up 26% to $166.5 million; immunoassays up 14% to $129.4 million

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DX Earnings Report, *from page 3*

COMPANY	FY 2019 Q3			DX Segment Performance
	Total Revenue (vs. Wall Street)	YOY Revenues	EPS (vs. Wall Street)	
Bio-Rad Laboratories	$560.6 million ($565.0 million)	+3%	Non-GAAP +$1.61 (+$1.40)	DX up 2% to $341.8 million driven by quality controls, immunology and blood typing product lines; net loss of $258.8 million as a result of investment losses
Bio-Techne (FY 2020 Q1)	$183.2 million ($179.4 million)	+12%	Adjusted +$1.06 (+$1.05)	DX & Genomics up 16% to $42.6 million despite negative impact on operating margin from Exosome Diagnostics acquisition
Bruker	$521.1 million ($496.7 million)	+12%	Non-GAAP +$0.43 (+$0.38)	CALID, including mass spectrometry and microbio, up in low teens
CareDx*	$33.8 million ($33.1 million)	+60%	-$0.19 (-$0.19)	Testing services up 68% to $28.2 million driven by 11% increase in AlloSure and AlloMap sales
Castle Biosciences	$14.8 million ($9.5 million)	+300%	Net +$0.05 (-$0.30)	DecisionDx-Melanoma skin cancer tests delivered up 30% to 4,482; DecisionDx-UM test reports up from 324 to 356
Danaher	$5.04 billion ($5.02 billion)	+4%	Adjusted +$1.16 (+$1.15)	DX up nearly 7% to $1.60 billion; Sciex and mass spectrometry down slightly as compared to unusually strong Q3 2018 sales and gap between new product launches; life sciences up from $1.60 to $1.70 billion; Beckman Coulter DX revenues up in mid-single digits for fourth quarter in a row driven by DxH 900 hematology analyzer and Dx 5000 laboratory automation system
Exact Sciences	$218.8 million ($216.1 million)	+85%	-$0.31 (-$0.41)	Cologuard test volume up 89% (456,000 people screened, 12,000 MDs ordered) with revenue per test down $13 to $479 per test (projected to be $480 in Q4) and average cost per test down $10 to $114; Company acquired by Genomic Health during quarter
Fluidigm**	$26.4 million ($28.7 million)	-9%	Adjusted -$0.09 (-$0.20)	Loss driven by 13% dip in mass cytometry to $15.6 million and 2% dip in microfluidics to $10.9 million
GenMark Diagnostics	$20.9 million ($20.4 million)	+32%	Net -$0.20 (-$0.19)	Growth driven by 98% increase in ePlex systems to $13.4 million (51 new systems placed during quarter), representing 64% of total revenues
Genomic Health	$114.4 million ($112.2 million)	+11%	Net +$0.48 (+$0.37)	US cancer test sales up 11% to $95.3 million, (39,340 OncotypeDx tests v. 34,810 in Q3 2018), including $82.4 million in breast cancer and $9.4 million in prostate cancer
Guardant Health*	$60.8 million ($45.4 million)	+181%	Net -$0.14 (-$0.37)	Testing volume + revenues per test both increase. Precision oncology up 185% to $52.1 million; development services up 156% to $8.7 million driven by new companion Dx products for biopharma
Hologic (FY Q4)	$865.8 million ($845.7 million)	+6%	Adjusted +$0.65 (+$0.65)	Global DX up 6% to $288.9 million driven by 9% growth in molecular diagnostics to $172.1 million and blood screening up 30% to $158 million but cytology + perinatal stay flat 1% at $118 million

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COMPANY	FY 2019 Q3			DX Segment Performance
	Total Revenue (vs. Wall Street)	YOY Revenues	EPS (vs. Wall Street)	
Invitae	$56.5 million ($55.0 million)	+51%	Non GAAP -$0.69 (-$0.56)	All testing segments up, including cancer, noninvasive prenatal screening and Detect pharma-sponsored testing; wider coverage helps offset PAMA gains with 73% of revenues from third party payors
LabCorp	$2.93 billion ($2.91 billion)	+4%	Adjusted +$2.90 (+$2.85)	Growth driven by acquisitions including Covance drug development; DX flat with less than 1% growth ($1.76 billion) as PAMA produces -1.5% impact; organic volume up less than 1% with managed care contracting changes producing -1% impact
Luminex**	$78.7 million ($81.8 million)	+9%	Net -$0.04 (-$0.03)	Still transitioning from loss of LabCorp accounts and integration of newly acquired MilliporeSigma flow cytometry business. Consumables up 15% to $13.4 million + molecular sample-to-answer revenues increase to $17.4 million
MDxHealth (cumulative revenues for first 9 months)	$15.6 million	-35%	Net -$0.35, as opposed to -$0.40 thru Q3 2018	ConfirmMDx prostate cancer test volume down 13% to 13,037 tests due to non-recurring volume spike from utility study done in Q3 2018—overall billable test volume for quarter up 5% to 4,305
Meridian Bioscience (FY Q4)	$50.8 million ($50.6 million)	-4%	Adjusted +$0.13 (+$0.09)	DX down 9% to $33.4 million, including 21% dip in molecular tests to $7.7 million and 6% dip in immunoassay and blood chemistry to $27.3 million; losses driven competitive pressures + price declines for gastrointestinal products
Myriad Genetics (FY 2020 Q1)**	$186.3 million ($202.1 million)	-8%	Adjusted +$0.08 (+$0.32)	Unfavorable CPT code changes for hereditary cancer tests drive molecular DX down 9% to $172.0 million, including 10% drop in hereditary cancer ($104.5 million), 15% decline in Vectra ($11.0 million), 4% drop in EndoPredict ($2.3 million); but prenatal testing up 30% to $23.5 million and Prolaris up 5% to $6.2 million
NanoString Technologies*	$30.6 million ($28.1 million)	+7%	Net -$0.64 (-$0.54)	Total IVD consumables up 14% to $12.7 million but Prosigna flat at $2.5 million; instruments up from $5.4 to $8 million
NantHealth	$22.4 million	+1%	Adjusted -$0.15, v. -$0.89 in Q3 2018	Insurance reimbursement losses lead to significant reduction in GPS molecular tests with overall 63% decline in molecular revenues to $276,000
Natera	$77.9 million ($74.0 million)	+19%	Net -$0.33 (-$0.54)	Driven by growth in Panorama noninvasive prenatal and Horizon carrier screening tests; tests processed up 20% to 200,200, most of which processed via Constellation software platform
NeoGenomics*	$104.7 million ($99.1 million))	+50%	Adjusted +$0.07 (+$0.06)	Fifth consecutive quarter of positive revenue growth, which occurs across all testing modalities, including over 50% growth in next-gen sequencing and molecular testing est volume up 35% to 250,518 + average revenue per test up 15% to $369 thanks to Genoptix acquisition and favorable test mix

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DX Earnings Report, *from page 5*

COMPANY	FY 2019 Q3			DX Segment Performance
	Total Revenue (vs. Wall Street)	YOY Revenues	EPS (vs. Wall Street)	
OpkoHealth	$228.8 million ($225.4 million)	-8%	Net -$0.11 (-$0.11)	PAMA reimbursement cuts hurt; 4Kscore prostate cancer tests slightly down from 18,700 to 18,000) but GeneDX strong with 6% growth in test volume fueled by 21% increase in hospital- + health-system-based test orders
Oxford Immunotec	$21.2 million ($20.3 million)	+32%	Pro forma +$0.04 (-$0.03)	US revenues nearly double to $5.8 million driven by higher tuberculosis testing volume, price increases + accounting adjustments% to $18.7 million due not just to strong demand but shift of higher seasonal testing volumes previously recognized in Q3; services down 44% to $922,000 due to exit from blood donor screening business
Pacific Biosciences	$21.9 million ($27.0 million)	+21%	Net -$0.19 (-$0.15)	$18.5 million in product + $3.4 million in service and other revenues, as firm awaits regulatory clearance for Illumina merger
PerkinElmer	$706.9 million ($715.9 million)	+5%	+$1.06 (+$1.01)	DX up 4% to $280.0 million driven by immunodiagnostics + reproductive health
Personalis	$17.2 million ($15.8 million)	+47%	Net -$0.22 (-$0.25)	US Dept of Veterans Affair contract continues to account for 75% of revenues
Qiagen**	$382.7 million ($383.2 million)	+1%	Adjusted +$0.36 (+$0.36)	Molecular DX down 3% to $183 million due in part to discontinuation of China NGS joint venture
Quanterix	$14.9 million ($12.6 million)	+41%	Not reported	Products up from $6 million to $10.7 million + services and other revenues up 39% to $4.2 million, including 40% growth in lab services
Quest Diagnostics*	$1.96 billion ($1.94 billion)	+4%	Adjusted +$1.76 (+$1.71)	5.1% increase in test volume offsets 2.5% decline in unit price, 120 basis points of which was caused by PAMA; Drivers of volume increase include drug monitoring, TB, STD and cardioIQ testing
Quidel	$126.5 million ($125.6 million)	+8%	Adjusted +$0.70 (+$0.64)	Rapid immunoassays up 20% to $42.5 million driven by 36% increase in influenza products to i$29.3 million; Cardiac immunoassays up 2% to $66.8 million; Molecular DX up 1% to $12.5 million, including 26% increase in Solana sales; Specialized DX up 13% to $14.3 million
Roche Diagnostics* (cumulative diagnostics revenues for first 9 months)	$9.53 billion	+4%	Not reported	Centralized + point-of-care (POC) up 5% to $5.78 billion, including 7% growth in molecular to $1.55 billion) driven by 9% increase in blood screening + strong demand for sequencing sample prep + microbiology; POC solutions up 26% + virology up 1%
Siemens Healthineers (FY Q4)	$4.64 billion	+8%	Net +$0.55	DX up 2% to $1.22 billion (€1.11 billion) driven by strong growth in Australia, China + rest of Asia which offset soft sales in Americas
10x Genomics	$61.2 million ($54.9 million)	+67%	Net -$0.33	Firm goes public in June. Consumables up 86% to $49.7 million, instruments up 13% to $10.4 million + services up 80% to $1.1 million

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COMPANY	FY 2019 Q3			DX Segment Performance
	Total Revenue (vs. Wall Street)	YOY Revenues	EPS (vs. Wall Street)	
Thermo Fisher*	$6.27 billion ($6.18 billion)	+6%	Adjusted +$2.94 (+$2.87)	Specialty DX down 2% to $879 million due to divestment of Anatomical Pathology business in June; Lab products + services up 6% (6% organic) to $2.62 billion driven by growth across segment led by pharma services
Trinity Biotech	$24.6 million	+4%	Net +$0.043	Clinical lab up 1% to $20.7 million + POC up 33% to $3.9 million driven by higher HIV sales in Africa which offset decline in US HIV sales
Veracyte	$31.0 million ($30.1 million)	+32%	Net -$0.02 (-$0.07)	Genomic test volume up 24% to 9,941 tests, including 25% growth in Envista Genomic Classifier (223 tests) + 17% growth in Affirma (8,925 tests)
Waters**	$577.3 million ($588.9 million)	- under 1%	Non-GAAP +$2.13 (+$2.13)	Hurt by currency translation + 4% drop in US sales

Companies that met or exceeded average Q3 Wall Street revenue estimates

* Companies that raised their revenue or EPS guidance during Q3

** Companies the lowered their revenue or EPS guidance during Q3

FDA Watch: Agency Clears the Way for Approval of Blood-Based PSA Test

The U.S. Preventive Services Task Force (USPTF) recommends that men age 55 to 65 consider prostate cancer screening. The reason it doesn't directly recommend testing for all men in this age group is that current screening methods that rely on detecting high levels of prostate specific antigen (PSA) in the blood are notoriously unreliable. High PSA levels may be a sign of not only prostate cancer but infection, inflammation or other disease. Another problem with current PSA PSA testing is that it over detects for low-grade cancer that don't pose a threat to the patient but result in unnecessary biopsies or treatment that does more harm than the actual cancer.

The New Blood-Based PSA Test

On Oct. 17, 2019, Cleveland Diagnostics, Inc., a company partly owned by the Cleveland Clinic dedicated to developing next-generation diagnostic tests for early cancer detection, announced that it has received FDA breakthrough device for a test that uses a new and more accurate methodology for detecting prostate cancer risk: The so-called IsoPSA test doesn't simply measure PSA levels but evaluates structural changes to the PSA protein allowing for more accurate differentiation between cancer and non-cancerous conditions; it is also capable of identifying whether cancer detected is serious and needs to be treated or benign enough to be

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FDA Watch, *from page 7*

left under "active surveillance." Securing FDA breakthrough designation expedites the approval process and brings Cleveland Diagnostics significantly closer to its goal of getting final approval to market the test in the U.S. in 2020.

Genetic Tests for Early Prostate Cancer Detection

When and if it reaches the market, IsoPSA faces competition from commercially available genetic tests using biomarker detection and algorithm technologies to assess a patient's risk of prostate cancer and avoid unnecessary biopsies. Such products include:

- Prostate Health Index (PHI) (Beckman Coulter), which uses a mathematical formula calculating prostate cancer probability by combining PSA, free PSA and p2PSA tests into a single score;
- 4Kscore (OPKO Health), which calculates a patient's percentage risk for aggressive prostate cancer by combining four prostate-specific kallikrein assay results with clinical information in an algorithm;
- SelectMDx (MDxHealth), a urine test that measures the expression of two mRNA cancer-related biomarkers that, when combined with the patient's clinical risk factors, provides a score assessing whether patient needs a biopsy or active surveillance;
- ExoDx Prostate (IntelliScore), aka, The EPI Test (Exosome Diagnostics), which analyzes a urine sample for three biomarkers of aggressive prostate cancer and uses an algorithm to assess the results and generate a score for use in determining whether a biopsy is necessary; and
- Mi-Prostate Score (MiPS) (Michigan Medicine), which combines the amount of serum PSA with the amounts of two genes for prostate cancer in the patient's urine for early prostate cancer detection

New FDA Approvals

Here's a look at other new FDA product approvals announced between late October and mid-November:

NEW FDA APPROVALS

Manufacturer(s)	Product(s)
NantHealth	510(k) clearance for Omics Core technology to measure overall tumor mutational burden in cancer tissue and report somatic mutations in 468 cancer-relevant genes
Siemens Healthineers	Clearance for Atellica IM Total hCG assay for quantitative measurement of human chorionic gonadotropin in human serum or plasma, using firm's Atellica IM Analyzer
Thermo Fisher Scientific	Clearance received clearance for iSensititre 18-24 hour MIC or Breakpoint Susceptibility System with Imipenem-Relebactam in dilution range of 0.03/4-256/4 µg/mL
DiaSorin	Marketing clearance for Liaison XL Zika Capture IgM Assay II for detecting Zika virus IgM antibodies previously cleared for emergency use only

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Manufacturer(s)	Product(s)
DiaSorin	Clearance Liaison Vitamin B12 chemiluminescent immunoassay for quantitative measurement of vitamin B12 on Liaison XL analyzer
Microbiologics	Clearance for Cepheid Xpert Respiratory Control Panel
iXensor	Clearance for PixoTest POCT Analyzer and PixoTest A1c Test Kit for quantitative measurement of glycated hemoglobin (HbA1c) in fingerstick capillary and venous whole blood samples
Fujirebio Diagnostics	Clearance for Lumipulse G CA19-9-N chemiluminescent enzyme immunoassay for quantitative measurement of CA19-9 in human serum or plasma, running on firm's Lumipulse G System
Lin-Zhi International	Clearance for LZI Methadone II Enzyme Immunoassay for qualitative and semi-quantitative determination of methadone in urine
Horiba	Clearance for Yumizen C1200 CRP reagent for quantitative measurement of C-reactive protein in human serum and plasma based on immunoturbidimetric assay
GeneOhm Sciences Canada	Clearance for BD Max Vaginal Panel running on BD Max System
NG Biotech	Clearance for NG-Test Carba 5 multiplex immunochromatographic assay to detect carbapenemase enzymes in bacterial colonies
Alpco	Clearance for Calprotectin Chemiluminescence ELISA for quantitative measurement of fecal calprotectin
MRIGlobal	Clearance for Applied Biosystems Bacillus anthracis Detection Kit
Exact Sciences	Breakthrough device designation for hepatocellular carcinoma test
Vela Diagnostics	Clearance for Sentosa SQ HIV Genotyping Assay, NGS-based HIV-1 drug resistance mutation assay
Affinimark Technologies	Breakthrough device designation for cerebrospinal fluid test strip
Myriad Genetics	Approval of myChoice CDx as companion diagnostic for determining patient's homologous recombination deficiency (HRD) status and who can benefit from niraparib (GlaxoSmithKline's Zejula)

New CE Marks & Global Certifications

Notable European CE certifications announced during the period:

NEW CE MARKINGS IN EUROPE

Manufacturer(s)	Product(s)
Paige	CE marking for Paige Prostate solution and Insight viewer AI-based prostate cancer detection products
Bioneer	CE marking for AccuPower HCV Quantitative RT-PCR Kit quantifying HCV viral RNA from blood samples using ExiStation, Bioneer's semi-automated real-time qPCR molecular diagnostic system
Biocept	CE marking for CEE-Sure blood collection tube and CEE-Sure sample collection shipping kit
Proscia	CE marking for Concentriq Dx digital pathology software for use in primary diagnosis
BioGx	CE-IVD marking for expanded respiratory infection assay called OSR for BD Max

Other international clearances announced during the period:

Manufacturer(s)	Country(ies)	Product(s)
FindGene Clinical Laboratories	China	National Medical Products Administration approval for noninvasive prenatal screening test kit
Biolidics	China	National Medical Products Administration Class I registration for ClearCell FX1 liquid biopsy platform that separates and enriches cancer cells from a blood sample

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The DX Pipeline : A roundup of the month's key new product launches

The last quarter is typically the busiest of the year for new product launches and 2019 is no exception. The DX pipeline was churning at a high pace from late October to mid-November. Here's a rundown of the key product launches announced during the period.

NEWLY LAUNCHED PRODUCTS & SERVICES	
Company(ies)	Product(s)/Service(s)
MedGenome	South Asian Research Genotyping Array database
Takara Bio	Cellartis Intestinal Epithelial Cells (from ChiPSC18) Kit
CBR (in collaboration with Sema4)	ReadyGen genetic screening test analyzing a child's DNA for over 200 conditions that can affect children before age 10
NuProbe Global	VarTrace Sanger assays for ultrasensitive detection and quantification of cancer mutations with variant allele frequencies
Loop Genomics	Amplicon library prep kit and service for generating synthetic long sequence reads from long PCR amplicons on Illumina sequencers
Loop Genomics	New service for linked read microbiome sequencing for studies with large cohorts
Grifols	AlphaID, cheek swab for screening patients with chronic obstructive pulmonary disease for alpha-1 antitrypsin deficiency
Akoya Biosciences	Motif PD-1/PD-L1 panels for profiling immuno-oncology biomarkers in the tumor microenvironment
Ceres Nanosciences	Nanotrap Virus Capture Kit
Ultivue	UltiMapper I/O T-reg kit for identifying regulatory T cells and cytotoxic T cells within the tumor context
Qiagen	QiaSeq Multimodal Panels, for simultaneous preparation of DNA and RNA libraries for next-generation sequencing
Lifebit Biotech	Lifebit CloudOS, a clorud-native, federated genomics operating system
Genomenon	Version 2.0 of Mastermind genomic search engine
Agena Bioscience	VeriDose CYP2D6 CNV panel for PGx testing
Paragon Genomics	CleanPlex CFTR Panel for cystic fibrosis testing
Genome Medical	Genome Care Delivery, cloud-based platform providing virtual access to nationwide network of clinical genetics specialists
SeraCare Life Sciences	Genomic DNA and formalin-fixed paraffin-embedded reference materials for tumor mutational burden measurement by NGS assays
Becton Dickinson	BD Rhapsody Whole Transcriptome Analysis Amplification Kit
Thermo Fisher Scientific	Oncomine Comprehensive Assay Plus for detection of targeted and immuno-oncology biomarkers
Yourgene	Yourgene Flex Analysis Software
RareCyte	RarePlex Staining Kit for evaluating prostate cancer specific expression of ARv7 on circulating tumor cells
DxTerity Diagnostics	IFN-1 Test for determining a systemic lupus erythematosus patient's type 1 interferon status and risk of progressing to lupus nephritis
New England Biolabs	NEBNext Globin and rRNA Depletion Kit
NYU Langone Health's Perlmutter Cancer Center	Clinical whole-genome DNA methylation profiling for patients with brain tumors
Biocartis	Idylla ctEGFR Mutation Assay
Synthego	Genome engineering service for induced pluripotent stem (iPS) cells

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Diagnostic Deals, *from page 1*

Illumina will keep pumping cash into struggling PacBio in the hopes of consummating the acquisition.

The other big development was the closing of Exact Sciences' acquisition of fellow cancer genetics testing firm Genomic Health. The merged companies will be restructured as a four-unit business with separate teams managing Exact's Cologuard business, Genomic Health's Oncotype DX business, international business initiatives and combined pipeline opportunities.

Here's a summary of key diagnostic deals announced from late October through the third week of November:

MERGERS, ACQUISITIONS & ASSET SALES

Acquiring Company	Target(s)	Deal Summary
Illumina	Pacific Biosciences	• Price: $1.2 billion cash ($8 per share, representing 71% premium over market for 30 days ending Oct. 31, 2018) • Status: Closing delays due to antitrust regulatory concerns in UK (see above) • PacBio long-read sequencing technology complements Illumina short-read sequencing platforms and enables it to provide integrated workflows and innovations that leverage both technologies
Exact Sciences	Genomic Health	• Price: $2.8 billion in cash and stock • Status: Closed • Genomic Health common shareholders to get per share price of $27.50 in cash and $44.50 in shares of Exact stock, subject to 10% collar based on Exact's volume-weighted average price for 45 trading days ending July 26 • Create cancer DX megafirm that unites Exact's Cologuard with Genomic Health's Oncotype DX
Invitae	Clear Genetics	• Price: $50 million—half in cash, half in common stock • Status: Closed • Invitae secures access to Clear Genetics' chatbot Gia, or Genetic Information Assistant, which is already being used by customers ordering genetic testing via Invitae's direct channel
Abcam	Expedeon	• Price: €120 million ($130 million) cash • Status: Deal requires Expedeon shareholder approval at meeting to be held Dec. 19 • Abcam to acquire Expedeon's core proteomics business + immunology-focused subsidiaries (Innova Biosciences + TGR Biosciences) • Expedeon plans to change its name + focus on genomics operations • Expedeon to keep its San Diego-based operations
Discovery Life Sciences	QualTek Molecular Laboratories	• Price: Undisclosed • Status: Closed • Acquisition of immunohistochemistry services provider broadens range of Discovery's histopathology services + supports development of innovative flow cytometry + cell-based lab services

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Diagnostic Deals, *from page 11*

MERGERS, ACQUISITIONS & ASSET SALES		
Acquiring Company	Target(s)	Deal Summary
Edan Diagnostics	LGC	• Price: Undisclosed • Status: Closed • Edan acquires LGC's Clarilight molecular diagnostics, point-of-care platform • Firms also to partner to develop molecular diagnostic assays designed for Clarilight with Edan to develop, manufacture, market and sell the instrument + test cartridges
LabCorp	South Bend Medical Foundation (SBMF)	• Price: Undisclosed • Status: Closed • LabCorp acquires SBMF's diagnostic clinical lab testing business in Indiana

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	Partner(s) 2+	Deal Summary
Agilent Technologies	MGI Tech	• Objective: Integrate Agilent's laboratory information management system with MGI's sequencing platforms • Dynamic: Combine Agilent's SLIMS system + MGI's DNBSeq sequencing platforms + life science instruments to seamlessly connect hardware + software
Agilent Technologies	Akadeum Life Sciences	• Objective: Develop new method of isolating target molecules for analytical workflows • Dynamic: Akadeum to apply its new technology that uses microbubbles to separate molecules + circulating tumor cells in liquid biopsies for downstream applications
Centogene	Pfizer	• Objective: Enable Pfizer to use Centogene's rare disease data repository to develop new drugs • Dynamic: Centogene to help Pfizer mine depository data + substantiate resulting data in exchange for an unspecified upfront payment • Centogene also eligible for future payments for any additional collaborative research projects
Promega	Merck	• Objective: Develop on-label, solid tumor companion diagnostic for Merck's anti-PD1 immunotherapy pembrolizumab (Keytruda) using Promega's microsatellite instability (MSI) technology • Dynamic: Global collaboration in which firms to seek regulatory approval for Promega MSI CDx in US, China + maybe other countries in the future
SomaLogic	Novartis	• Objective: Leverage SomaLogic's SomaScan proteomics platform to develop new drugs • Dynamic: Under 10-year deal, SomaLogic to analyze at least 250,000 clinical samples provided by Novartis + use resulting data for its own proteomic test development work • Firms have partnered since 2011
Proscia	Dell Technologies	• Objective: Develop cost-effective, scalable IT infrastructure for deploying digital pathology solutions • Dynamic: Collaboration to provide reference architectures for whole-slide image viewing and managing, including Proscia's Concentriq platform
Oncimmune	Biodesix	• Objective: Commercialize EarlyCDT Lung in US • Dynamic: Biodesix to acquire Oncimmune CLIA lab facilities in Kansas + pay Oncimmune $1.0 million in quarterly instalments of $250K • Oncimmune grants Biodesix option (exercisable by the end of 2020) to commercialize EarlyCDT Lung as screening diagnostic for lung cancer in US in exchange for a further cash payment • Biodesix gets right to renew for additional 5 years

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STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	Partner(s) 2+	Deal Summary
Illumina	Lexent Bio	• Objective: Develop in vitro diagnostic kit for cancer • Dynamic: Non-exclusive partnership under which Lexent will develop its Confera Dx assay, NGS-based kit for monitoring response to therapy or minimal residual disease in patients with certain solid tumors, to run on Illumina's NextSeq 550Dx system • Lexent responsible for securing regulatory approvals + commercializing kit
Thermo Fisher Scientific	Owlstone Medical	• Objective: Discover + validate early cancer detection biomarkers by noninvasive breath sampling • Dynamic: Thermo Fisher to qualify its mass analyzers for detection of new biomarkers by integrating its Q Exactive GC Hybrid Quadrupole-Orbitrap gas chromatography mass spectrometer (GC-MS) into Owlstone's Breath Biopsy platform
Thermo Fisher Scientific	Genialis	• Objective: Create integrated workflow to ease the data-analysis bottleneck for RNA sequencing • Dynamic: Comarketing agreement integrating Thermo Fisher's Invitrogen Collibri Stranded RNA Library Prep Kit for Illumina NGS systems with Genialis' Expressions analysis software
Thermo Fisher Scientific	Milu Labs	• Objective: Develop clinical diagnostic technologies for women's health in China • Dynamic: Use Thermo Fisher's liquid chromatography-mass spectrometry instrumentation to develop tools assessing risk for adverse pregnancy outcomes, including a clinical mass spectrometry-based proteomics assay
Lucence Diagnostics	MEDx (Suzhou) Translational Medicine	• Objective: Develop cancer-related companion diagnostic tests for China • Dynamic: Tests to be codeveloped for PD-L1 rearrangement to be used with anti- PD1/PD-L1 cancer immunotherapies
Abcam	BrickBio	• Objective: Use BrickBio's bioconjugation platform to develop research + diagnostic products • Dynamic: Abcam gets exclusive right to use platform to create conjugation-ready recombinant products for research tools market • Abcam also gets right to commercialize platform across its recombinant antibody + protein portfolio • Abcam also gets undisclosed equity stake in BrickBio
SpeeDx	QuantuMDx + Foundation for Innovative New Diagnostics (FIND)	• Objective: Assess feasibility of porting SpeeDx sexually transmitted infection tests to the QuantuMDx point-of-care testing device • Dynamic: SpeeDx to use its PlexPCR technology to develop multiplex tests for common STIs, including gonorrhea and Mycoplasma genitalium, to be run on QuantuMDx Q-POC device with FIND to fund project
Targos Molecular Pathology	Ultivue	• Objective: Provide standardized multiplex phenotypic assays to pharmaceutical companies for characterization of samples selected for clinical research programs • Dynamic: Leverage Ultivue's UltiMapper assays, which are used in tumor immune-profiling research strategies to demonstrate clinical utility of panels of markers
Hitachi	Centre Léon Bérard (CLB)	• Objectives: i. Develop diagnostic imaging technologies to detect cancer sites + improve diagnosis from CT + MRI scans; ii. Identify biomarkers from genomic data to predict response to radiation treatment • Dynamic: Establish new research laboratory called The Hitachi Lyon Lab, housed at CLB's facilities in France
OptraHealth	InformedDNA	• Objective: Make InformedDNA's network of genetic counselors remotely available to users of OptraHealth GeneFax system • Dynamic: Telegenetics partnership enabling consumers on the GeneFax Counselor Connect scheduling platform to reach InformedDNA counselors online to ask questions about genetic + prenatal testing

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Diagnostic Deals, *from page 13*

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	Partner(s) 2+	Deal Summary
Mission Bio	BioLegend	• Objective: Provide simultaneous DNA analysis + protein detection in single cells • Dynamic: Codevelop a sample preparation solution for Mission Bio's Tapestri platform + create hematology-focused catalog panel to launch in 2020
Qiagen	Repertoire Genesis	• Objective: Develop companion diagnostic tests on Illumina sequencing platforms that use Repertoire Genesis' TCR technology in immuno-oncology • Dynamic: Non-exclusive worldwide cross-marketing + promotion agreement under which Repertoire Genesis to give Qiagen access to technologies for development of T cell + B cell receptor repertoire sequencing assays
Akoya Biosciences	Precision for Medicine (formerly ApoCell)	• Objective: Develop liquid biopsy + tissue biomarker assays using Akoya's Vectra Polaris system • Dynamic: Combine Vectra Polaris system with Precision for Medicine's ApoStream technology, using both tumor biopsies + liquid biopsies to generate data for assessing drug efficacy + validating companion diagnostics
Sysmex	Optim	• Objective: Form joint venture to develop and operate digital medicine platforms • Dynamic: Latest initiative of business alliance created in Feb. 2019 to combine Sysmex's global sales + service network with Optim's AI + data management technologies, including the Optim Cloud IoT OS • Joint venture to develop + test new diagnostic methods that combine image information from gene tests with AI analysis • Joint venture to collaborate with pharma companies + medical device manufacturers
Sienna Cancer Diagnostics	Minomic International	• Objective: Develop test for early detection of pancreatic cancer • Dynamic: Sienna to use NET molecular capture technology it acquired in April 2019 + also provide Exo-NET beads, an exosome capture technology
Twist Bioscience	MGI International Sales (BGI subsidiary)	• Objective: Comarket Twist's sequencing target enrichment products in Europe + Asia Pacific • Dynamic: Under non-exclusive agreement, firms to make Twist's NGS target enrichment kits available on MGI's sequencing platforms • Covered products include the Twist Human Core Exome, Twist Mouse Exome, Twist RefSeq, Twist Universal Blockers, Twist Fast Hybridization and Wash kits, and Twist's custom panels
Mologic	Sherlock Biosciences	• Objective: Develop tests that combine lateral flow + molecular diagnostic technologies for use in low-resource settings + the home • Dynamic: Collaboration aiming to collaboration aims to advance affordable platforms for detecting DNA or RNA targets in virtually any decentralized site being funded via expansion of existing grant from The Bill & Melinda Gates Foundation
PredictImmune	KSL Biomedical	• Objective: Commercialize PredictImmune PredictSURE inflammatory bowel disease test in North America • Dynamic: Under exclusive commercial partnership, KSL to commercialize + facilitate fulfillment of orders for the test, and receive + process samples through its KSL Diagnostics testing lab
Microba	Psomagen (subsidiary of Psomagen)	• Objective: Launch microbiome analysis test in US before the end of 2019 • Dynamic: Microba recently launched Insight, a direct-to-consumer service in Australia that uses shotgun metagenomics to analyze customers' gut microbiomes + generate a personalized report
Biocartis	Nichirei Biosciences	• Products: Biocartis' Idylla products • Territory: Japan

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DISTRIBUTION, SALES & MARKETING AGREEMENTS		
Product Owner	Distributor	Deal Summary
Eurobio Scientific	CirrusDx	• Products: Eurobio's T-COR 8 molecular biology platform • Territory: France + Maghreb countries of North Africa, including Algeria, Libya, Mauritania, Morocco, Tunisia, Western Sahara
Pillar Biosciences	MGI Tech (subsidiary of BGI)	• Products: Pillar's Onco/Reveal next-generation sequencing panels • Territory: Comarketing deal covering outside the US
BillionToOne	Eluthia	• Products: BillionToOne's Unity noninvasive prenatal test • Territory: Germany, Austria, Switzerland, Netherlands • Exclusive
Nippon Genetics	GeneX India	• Products: Nippon Genetics' cell and molecular biology research products • Territory: India • Exclusive
Veritas Intercontinental	Genomika	• Products: Veritas' whole-genome and exome sequencing services • Territory: Brazil
Mobidiag	Alab	• Products: Mobidiag's Amplidiag and Novodiag molecular diagnostic products • Territory: Poland and Ukraine • Exclusive
Mobidiag	Biogenetix	• Products: Mobidiag's Amplidiag and Novodiag molecular diagnostic products • Territory: Romania • Exclusive
Mobidiag	Theranostica	• Products: Mobidiag's Amplidiag and Novodiag molecular diagnostic products • Territory: Israel • Exclusive
PredictImmune	Theradiag	• Products: PredictSure IBD test • Territory: France, Belgium, Luxembourg, Switzerland, Maghreb countries in northwest Africa • Exclusive licensing, promotion + distribution partnership
MDNA Life Sciences	Mediwell Enterprise	• Products: MDNA's PCR-based Mitomic Prostate Test (MPT) liquid biopsy assay • Territory: Singapore, Malaysia, Vietnam, Thailand, Brunei, Myanmar, Philippines, Indonesia • Exclusive
DNAStar	Inqaba Biotechnical Industries	• Products: DNAStar's Lasergene DNA, RNA and protein sequence analysis software • Territory: Africa

LICENSES		
Licensor	Licensee	Deal Summary
University of Pittsburgh Medical Center	Sonic Healthcare USA	• 15-year agreement expanding existing exclusive license allowing Sonic to offer the ThyroSeq Genomic Classifier test at all of its US clinical labs and anatomic pathology practices • Previously, Sonic could offer the test only through its CBLPath division
University of Bonn	Qiagen	• Qiagen licenses epigenomic biomarkers based on immune checkpoint gene methylation • Qiagen also gets rights to codevelopment of predictive companion diagnostics for use in selecting patients likely to benefit from immuno-oncology therapies
Stratifyer Molecular Pathology	Qiagen	Qiagen gets exclusive access to biomarker intellectual property providing guidance for treatment of bladder and, potentially, other urothelial cancers

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Diagnostic Deals, *from page 15*

W		
Supplier/Servicer	Client/User	Deal Summary
Quanterix	Siemens Healthineers	Quanterix to provide Siemens Healthineers access to neurofilament-light (Nf-L) antibodies for use in developing blood-based Nf-L clinical tests

NEW CLINICAL STUDIES		
DX Partner	Other Partner(s)	Description of Study
PredictImmune	Crohn's & Colitis Foundation	Study to validate PredictImmune's PredictSure IBD test by tracking up to 200 patients from 15 medical centers across the US who have Crohn's disease or ulcerative colitis and aren't receiving systemic steroids, immunomodulators or biologics
Inivata	European Organization for Research + Treatment of Cancer	Pfizer-funded Phase II trial using Inivata's InVisionFirst-Lung test to test lung cancer patients under being treated with the ALK inhibitor lorlatinib (marketed as Lorbrena)
ACT Genomics	University of California, San Diego Moores Cancer Center	Study to evaluate gene expression signals associated with tumor microenvironment that may predict outcome in melanoma patients treated with PD-1 inhibition
Guardant Health	NA	ECLIPSE trial (Evaluation of ctDNA Lunar Assay In an Average Patient Screening Encounter), a 10,000-patient observational study evaluating performance of firm's Lunar-2 circulating cell-free DNA test in detecting colorectal cancer in average-risk adults

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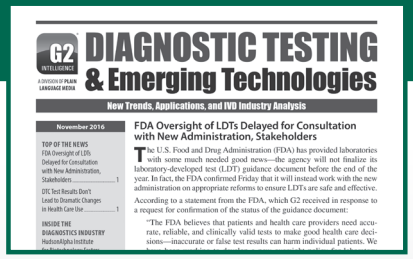

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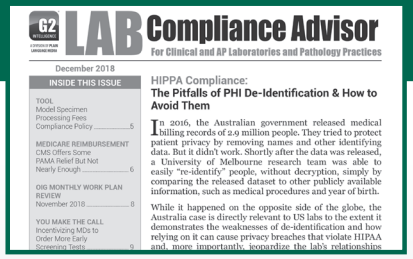

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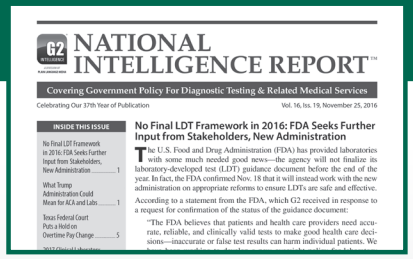

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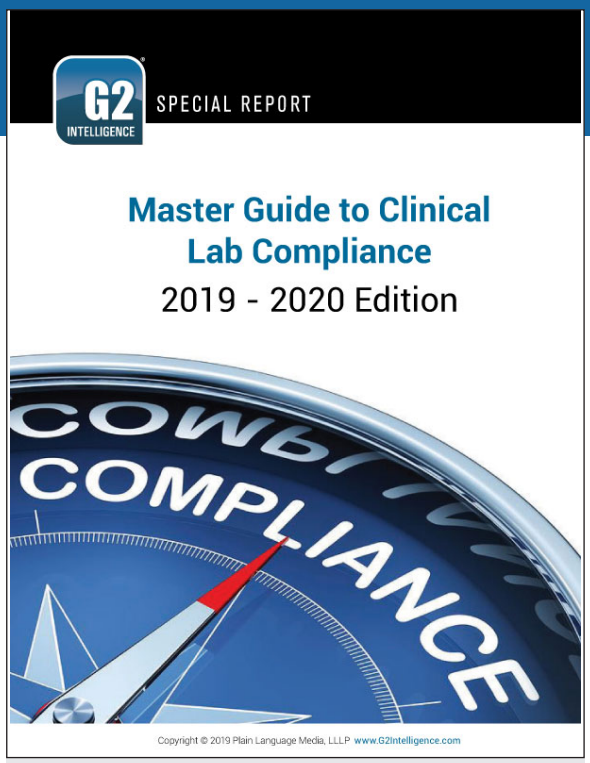

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