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Upcoming Events

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Oct. 24-26, Washington, DC

www.labinstitute.com

Lab Leadership Summits

■ *Lab Billing, Payments & Collections Summit*
Aug. 3, Denver, CO

■ *Lab Reimbursement Summit 2019*
Nov. 2018, Atlanta, GA,

www.lableadershipsummits.com

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

After last month's flurry of transactions, business calmed down as it often does during the start of summer. Here are the key deals and trends from mid-June through the third week of July.

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Investment Trends: Venture Capitalists Remain High on Healthcare

Healthcare startups remain highly attractive to venture capitalists drawing \$10.6 billion in investments in the first half of 2018, the most of any industry sector other than internet companies and well ahead of #3 on the list, mobile and telecommunications, according to a [new MoneyTree report](#) from PricewaterhouseCoopers and CB Insights. At this rate, healthcare will easily surpass the record of \$15 billion in total sector investment posted in 2017.

While the report does not break down the sector data, it does note that two of the biggest U.S. venture deals in the second half of 2018 were in the healthcare sector (See [NIR, February 2018](#), for analysis of healthcare sector venture investment flows):

Rank	Company	Industry	Deal Value	Funding Stage
4	Allogene Therapeutics	Biotechnology	\$300 million	Early stage
4	Grail Inc.	Disease DX	\$300 million	Expansion stage

Both companies are based in California and dedicated to cancer diagnostics and treatment. Grail's experimental blood screening test has showed early promise in detecting early-stage lung cancers based on free-floating DNA released by tumors. Allogene produces "off the shelf" enabling the engineering of cell therapies to kill cancer cells.

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■ Diagnostic Deals, from page 1

M&A

The year's biggest deal in the lab M&A space, Roche's \$2.4 billion acquisition of the 43% of Foundation Medicine that it does not currently own, progressed toward its scheduled 2018 closing with the launch of a tender offer for Foundation at \$137 per share, a premium of 29% over its June 18 market valuation. Once the tender offer closes on July 30, Roche will acquire the remaining shares via merger. Acquiring the molecular analysis and genomic profiling assets of its erstwhile collaborator, which will remain autonomous after the merger, has become a major part of Roche's strategy for bolstering its position in personalized healthcare.

Agilent Technologies continued its shopping spree by inking a deal to acquire privately-held glycan reagents producer ProZyme for an undisclosed price. This is the one-time Hewlett-Packard spinoff's fourth M&A deal of the year following the completion of its \$250 million purchase of Advanced Analytical Technologies and announced agreements to acquire Korean scientific instruments distributor Young In Scientific and chemical standards provider Ultra Scientific for undisclosed amounts.

Another big deal was Thermo Fisher Scientific's June 25 announcement of its deal to buy Roper subsidiary Gatan for \$925 million in cash. The electron microscope software manufacturer with 320 employees and roughly \$150 million in annual revenues will become part of Thermo Fisher's analytical instruments unit once the deal closes by year's end.

Strategic Alliances

Strategic collaboration was noticeably slow, in terms of both volume and impact with collaborations between diagnostics firms and academic institutions and nonprofits furnishing most of the impetus. Of course, there were a few deals pairing heavy hitters from the private sector, including the collaboration of:

- ▶ Illumina and PerkinElmer to codevelop metagenomic sequencing workflow enabling DNA extraction and sequencing from samples without the need to culture the bacteria
- ▶ Illumina and OrigiMed to develop new molecular oncology assays; and
- ▶ Bio-Rad and Bruker to comarket workflow solutions for pathogen detection and confirmation.

The other salient trend during the period was the trio of strategic alliances targeting the China market with Predicine, Agena Bioscience and Berlin, Germany-based CeGaT teaming with local partners to provide diagnostics services to the vast Chinese market.

The headliner on the consumer genetics front was Nutrisystem's partnering with Akesogen and Genetic Direction to launch DNA Body Blueprint, a genetic analysis test in which DNA from cheek swabs is used to generate personalized information on an individual customer's nutrition, metabolism and eating behaviors for use in tailoring individualized weight loss plans.

Here's a summary of all the key diagnostic deals from mid-June through the third week in July:

MERGERS, ACQUISITIONS & ASSET SALES		
Acquiring Company	Target(s)	Deal Summary
Roche	Foundation Medicine	<ul style="list-style-type: none"> Price: \$2.4 billion cash Status: Expected to close in second half of 2019 Deal furthers Roche's personalized healthcare strategy since molecular analysis and genomic profiling enable development of new cancer treatments
Agilent Technologies	ProZyme	<ul style="list-style-type: none"> Price: Undisclosed Status: Agreement to acquire with no closing date announced Acquisition of privately-held provider of glycan analysis reagents, kits and standards expands Agilent's portfolio of biopharma consumables in glycan market
Bruker	JPK Instruments	<ul style="list-style-type: none"> Price: Undisclosed Status: Closed Bruker acquires Berlin-based provider of microscopy instruments for biomolecular and cellular imaging, and force measurements on single molecules, cells and tissues with 2017 revenues of approximately €10 million (\$11.7 million)
Thermo Fisher Scientific	Gatan (wholly-owned subsidiary of Roper)	<ul style="list-style-type: none"> Price: \$925 million cash Status: Expected to close by end of 2018 Gatan, a California-based manufacturer of electron microscope instrumentation and software, to become part of Thermo Fisher's analytical instruments business unit
Biodesix	Integrated Diagnostics	<ul style="list-style-type: none"> Price: Undisclosed Status: Closed Acquisition of Seattle-based producer of XL2 lung cancer test previously known as Xpresys Lung
Bio-Techne	Exosome Diagnostics	<ul style="list-style-type: none"> Price: Up to \$575 million, \$250 million upfront and \$325 contingent Status: Agreement to acquire scheduled to close in July or August Techne will seek to leverage Exosome's technology to interpret complex gene expression data and find early predictors of disease progression
Locus Biosciences	EpiBiome	<ul style="list-style-type: none"> Price: Undisclosed Status: Closed Asset sale in Locus Biosciences acquires EpiBiome's high-throughput bacteriophage discovery platform which it intends to pair with its own CRISPR-based synthetic biology platform to develop antibiotic-resistant bacterial infection treatment products
Eurobio Scientific	Dendritics	<ul style="list-style-type: none"> Price: Cash deal at undisclosed price Status: Closed Acquisition of French firm that develops antibodies against immune system and other cells for discovery of targets with high diagnostic, prognostic and therapeutic potential that posted about €350,000 (\$410,000) in 2017 revenues
Kypha	Biosensia	<ul style="list-style-type: none"> Price: Undisclosed Status: Closed Acquired diagnostics platform and contract development company to operate as a wholly-owned subsidiary of Kypha
Now Diagnostics	Cellmic	<ul style="list-style-type: none"> Price: Undisclosed Status: Closed Asset sale under which Now Diagnostics mobile DX firm's rapid assay reader product lines Now Diagnostics to integrate Cellmic's advanced reader technology with its own Adex-usDx test platform

MERGERS, ACQUISITIONS & ASSET SALES		
Acquiring Company	Target(s)	Deal Summary
Precision Therapeutics	Helomics	<ul style="list-style-type: none"> ■ Status: Definitive agreement to merge ■ After taking 25% equity stake in Helomics last Dec., Precision to acquire remaining 75% with newly acquired shares to be converted into right to receive proportionate share of 7.5 million shares of newly issued Precision common stock ■ Merger contingent on exchange of at least 75% of Helomics' \$7.6 million in outstanding promissory notes for additional shares of Precision common stock at \$1 per share
Lab21 Products (protein diagnostics division of Novacyt)	Omega Diagnostics	<ul style="list-style-type: none"> ■ Price: Up to £2.2 million (\$2.9 million), including acquisition fee of £1.8 million upon completion, £175,000 after 12 months and £200,000 upon accreditation of Omega's production facility ■ Status: Agreement to acquire with no closing date announced ■ Lab21 to assume commercial rights to core registered brands including Immutrep, Avitex, Micropath, Pathozyme and some smaller brands ■ Omega gives Lab21 limited-time license to use name Visitect for lateral flow tests other than Omega's Visitect CD4 assets
Helix	HumanCode	<ul style="list-style-type: none"> ■ Price: Undisclosed ■ Status: Closed ■ Helix acquires Colorado firm that developed the BabyGlimpse and DNAPassport apps for the Helix platform
Vela Diagnostics	Great Basin Scientific	<ul style="list-style-type: none"> ■ Price: Undisclosed ■ Status: Definitive agreement with no closing date announced ■ Vela to add microbiology capabilities to its existing virology and oncology business, as well as Great Basin's six FDA-approved cartridge-based assays
STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	Partner 2	Deal Summary
PerkinElmer	Enzyvant	<ul style="list-style-type: none"> ■ Objective: Provide diagnostic testing for Farber disease ■ Dynamic: PerkinElmer Genomics lab and genetic testing unit to offer tests screening for mutations in ASAH1 gene
PerkinElmer	Women & Infants Hospital of Rhode Island	<ul style="list-style-type: none"> ■ Objective: Evaluate performance of noninvasive prenatal testing system that PerkinElmer acquired from Vanadis Diagnostics in 2016 ■ Dynamic: So called Value study (Validation of a Lower Cost Aneuploidy Screen) to test samples from 2,650 pregnant women to measure platform's performance in detection, false positives, turnaround time, associated costs, fetal sex determination and quality metrics
Illumina	OrigiMed	<ul style="list-style-type: none"> ■ Objective: Develop new oncology assays ■ Dynamic: Tests to be developed on Illumina's NGS instruments for cancer molecular diagnostics ■ OrigiMed also to develop a bioinformatics solution for medical institutions
Illumina	PerkinElmer	<ul style="list-style-type: none"> ■ Objective: Codevelop metagenomic sequencing workflow enabling DNA extraction and sequencing from samples without need to culture the bacteria ■ Dynamic: Workflow combines Illumina's Nextera DNA Flex library prep kit with PerkinElmer's automation
B. Braun China	CeGaT (Germany)	<ul style="list-style-type: none"> ■ Objective: Provide clinical genetic testing services in China ■ Dynamic: Newly formed B. Braun Precision Medicine Technology subsidiary in Shanghai to provide hereditary disease and oncology clinical genetic testing and counseling services ■ CeGaT to offer its full menu of diagnostics products in China with testing conducted at its labs in Germany and China
Agena Bioscience	Zhejiang Dian Diagnostics	<ul style="list-style-type: none"> ■ Objective: Commercialize Agena's MassArray system and DNA testing products in China ■ Dynamic: Dian to use MassArray system for molecular genetic testing ■ This is Agena's third strategic deal in China in past two years

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	Partner 2	Deal Summary
Predicine	Kintor Pharmaceuticals	<ul style="list-style-type: none"> Objective: Develop companion diagnostics for FDA approval in US and China Dynamic: Kintor to use Predicine's GeneRADAR liquid biopsy platform to improve its prostate, breast and liver cancer oncology products pipeline
Indivumed	Singapore's Agency for Science, Technology, and Research (A*STAR)	<ul style="list-style-type: none"> Objective: Perform proteomics research with aim of building out the IndivuType global cancer database Dynamic: A*STAR's Institute of Molecular and Cell Biology to perform proteomic and phosphoproteomic analyses on tissue samples from Indivumed cancer biobank with resulting data to be added to IndivuType
Bio-Rad Laboratories	Bruker	<ul style="list-style-type: none"> Objective: Comarket foodborne pathogen detection and confirmation workflow solutions Dynamic: Bio-Rad's RAPID chromogenic media that screens food products for pathogenic bacteria to be comarketed with Bruker's MALDI Biotyper for confirming and identifying the detected organisms
NuMedii	Yale School of Medicine + Brigham and Women's Hospital	<ul style="list-style-type: none"> Objective: Use single-cell RNA sequencing to identify new drugs and biomarkers for idiopathic pulmonary fibrosis, a chronic lung disease Dynamic: NuMedii, a Stanford Univ. AI spinout, to combine partner labs' patient single-cell RNA sequencing data with its own AI artificial intelligence technology
Beckman Coulter Diagnostics	University of California, Irvine	<ul style="list-style-type: none"> Objective: New DX product development Dynamic: Beckman Coulter to gain access to UCI research in diagnostic platforms, life science applications, devices and data analytics
Diversigen	Norgen Biotek	<ul style="list-style-type: none"> Objective: Combine services into a single end-to-end offering for microbiome research Dynamic: Combine Diversigen's microbiome and metagenomics consulting, sequencing and data analysis services with Norgen's RNA, DNA, protein purification and NGS sample prep products
BC Platforms	Tieto	<ul style="list-style-type: none"> Objective: Develop genomic data management technology Dynamic: Use Tieto's Lifecare line of healthcare technology to create platform for integrating clinical and genomic data that can be used to improve predictive and precision medicine
Evonetix	Durham University	<ul style="list-style-type: none"> Objective: Develop method for DNA synthesis Dynamic: £1.3 million (\$1.7 million) project funded partly by Innovate UK to use Evonetix's technology which uses an addressable silicon array to direct synthesis of DNA at many sites in parallel, followed by an error-detection process to allow scale assembly of high-fidelity DNA
Bayer	Broad Institute	<ul style="list-style-type: none"> Objective: Research causes of heart failure and identify new drug targets for condition Dynamic: Scientists from each organization to collaborate on developing high-resolution, single-cell maps of cardiovascular tissues in human and animal models Partners establish Precision Cardiology Laboratory at Broad where work will be done
Freenome	Medical University of Graz (Austria)	<ul style="list-style-type: none"> Objective: Create new lab at University to investigate cell-free DNA and other bloodborne molecules as cancer biomarkers for use in early detection and personalized treatment Dynamic: Lab to use Freenome's AI genomics technology to investigate role of cfDNA and other cell-free biomarkers in cancer
Genome.One	Clearbridge Health	<ul style="list-style-type: none"> Objective: Promote Genome.One's GoExplore personalized genomics service to Clearbridge customers in Asia Dynamic: Clearbridge clinicians to refer GoExplore to their patients in Singapore and Hong Kong
SingularityNet	Project Shivom	<ul style="list-style-type: none"> Objective: Combine blockchain technology, AI and genomics for medical analytics Dynamic: Leverage SingularityNet's commercial AI solutions with Project Shivom's expertise for harnessing blockchain technology for genomic information and analytics

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	Partner 2	Deal Summary
WIRB-Copernicus Group (WCG) (thru its Clinical Services Division)	InformedDNA	<ul style="list-style-type: none"> Objective: Create new "Center for Genetics and Precision Medicine in Clinical Trials" offering support services to biopharms, CROs and academic institutions in designing and conducting precision medicine clinical trials Dynamic: Combine InformedDNA's genetics resources and expertise with WCG's global network of clinical trial optimization experts and industry Knowledge Base
SD Biosensor	PATH	<ul style="list-style-type: none"> Objective: Develop diagnostic test for use in eliminating malaria Dynamic: Partners to continue development of their Standard G6PD test to guide clinical care of patients with Plasmodium vivax malaria who also have a hereditary enzyme deficiency that can result in severe anemia if they are treated with 8-aminoquinoline-based drugs for the infection Current test doesn't adequately determine G6PD status of woman who carry the gene for G6PD deficiency on only one X chromosome and have intermediate G6PD activity levels
DISTRIBUTION, SALES & MARKETING AGREEMENTS		
Property Owner	Distributor	Deal Summary
Akers Biosciences	Appleton Medical Services	<ul style="list-style-type: none"> Product: Akers' PIFA Heparin/PF4 Rapid Assay for rapid determination if patient being treated with the heparin blood thinner heparin at point of care may be developing thrombocytopenia Territories: 12 US states—Indiana, Kentucky, Minnesota, Illinois, Wisconsin, Mississippi, Louisiana, Missouri, Kansas, Iowa, Nebraska, Arkansas
HalioDx	Sohin	<ul style="list-style-type: none"> Product: HalioDx's Immunoscore Colon assay Territory: Mexico Exclusive
Biocept	Alliance Global	<ul style="list-style-type: none"> Products: Biocept's Target Selector liquid biopsy tests Territories: United Arab Emirates + select countries in Middle East, North and Sub-Saharan Africa and Southeast Asia
MNG Laboratories	Pronto Diagnostics	<ul style="list-style-type: none"> Products: MNG's neurogenetic clinical RNA sequencing services Territory: Israel Exclusive
DiaCarta	Arrow Diagnostics	<ul style="list-style-type: none"> Product: DiaCarta's ColoScape colorectal cancer test Territories: Italy, San Marino and Vatican City Exclusive
Namocell	Tomy Digital Biology	<ul style="list-style-type: none"> Product: Namocell's Namocell Single Cell Dispenser Territory: Japan
Molecular Biology Systems	Intas Science Imaging Instruments	<ul style="list-style-type: none"> Product: Molecular Biology's NextGen PCR thermal cycler Territory: Germany
LICENSES		
Licensor	Licensee	Deal Summary
GNS Healthcare	Somalogic	<ul style="list-style-type: none"> Property: GNS Healthcare's REFS (Reverse Engineering & Forward Simulation) causal machine learning technology Somalogic gets right to use REFS technology to analyze protein datasets generated by its SomaScan proteomic platform
Janssen Pharmaceutica	Saladax Biomedical	<ul style="list-style-type: none"> Property: Saladax gets right to acquire patent rights to Janssen Pharmaceutica's tests to determine drug levels in patients treated with antipsychotic drugs Exclusive

LICENSES		
Licensors	Licensee	Deal Summary
Beckman Coulter Diagnostics	Health Canada	<ul style="list-style-type: none"> Property: Beckman Coulter's Access Sensitive Estradiol assay Government agency gets right to give Canadian labs access to test for patient reproductive health management
Proteomics International Laboratories	Patia BioPharma	<ul style="list-style-type: none"> Property: Proteomics' PromarkerD test for diabetic kidney disease licensed for commercialization in Mexico Patia to develop and commercialize PromarkerD as a mass spec-based LDT performed by its partner, Clinica Ruiz Laboratories
SUPPLY, SERVICE & TESTING AGREEMENTS		
Supplier/Service	Client	Deal Summary
DNA Genotek	Simons Foundation Autism Research Initiative	<ul style="list-style-type: none"> Renewal of multi-year agreement to supply DNA Genotek's Oragene Dx saliva kits and GenoFIND custom collection kit packaging and order fulfillment services to Simons' Simons Foundation Powering Autism Research for Knowledge (SPARK) project

FDA Watch: Agency Confirms that LOINC Coding of IVD Tests Is Voluntary

On June 15, the FDA issued a [new guidance document](#) clarifying the rules for laboratory coding of *in vitro* diagnostic tests. There are four key takeaways for IVD test makers and labs:

1. No Mandatory Lab Coding of Tests

Laboratory coding is voluntary, not mandatory, according to the guidance. However, the FDA recommends that test makers use the Observation Identifiers Names and Codes (LOINC) for coding IVD tests.

2. No Mandatory Lab Coding of Devices

Similarly, the FDA is recommending but not requiring inclusion of LOINC codes for IVD tests in labeling of medical devices. The agency does not intend to perform premarket review of the LOINC codes that manufacturers provide to labs or other users.

3. LOINC Codes Must Be for Test's Approved Indications

According to the guidance document, the LOINC codes the device manufacturer provides should be consistent with the particular IVD test's FDA-cleared or approved indications for use. Dissemination of LOINC codes suggesting an unapproved or uncleared indication may be evidence that the device is adulterated and/or misbranded.

4. LOINC Code Distribution Format Neither Required nor Recommended

While declining to recommend a specific format for distribution, the agency "acknowledges" that LOINC codes may be displayed as simple text in a table format, or in structured formats such as Java Script Object Notification (JSON) or Extensible Markup Language (XML). However, the FDA "strongly encourages" use of an FDA-recognized consensus standard, e.g., the LOINC

transmission document for IVDs (LIVD) standard, for communicating or disseminating the LOINC codes provided by manufacturers or others to labs or other end users.

FDA Revises Zika Blood Testing Guidance

On July 6, the FDA issued [revised guidance](#) for testing of donated blood for Zika virus. *Punchline:* After initially recommending universal nucleic acid testing of individual blood donation units, the agency indicated that it will now allow pooled testing which the guidance described as more cost effective and “less burdensome” for blood establishments. However, the guidance continued, the need for individual testing may be triggered “when certain threshold conditions are present” such as an increased risk of local mosquito-borne transmission of Zika virus in a specific geographic area.

The final guidance still requires blood establishments to test all donated whole blood and blood components for Zika virus using a nucleic acid test. Since 2016 two assays have been approved under investigational new drug applications—the Cobas Zika (Roche Molecular Systems, Inc.) and the Procleix Zika Virus Assay (Grifols Diagnostic Solutions, Inc.). In May of this year, the FDA approved an additional claim for Roche’s Cobas Zika test for pooled testing of blood or plasma donations.

New FDA Approvals

A trio of Breakthrough Device designations headline the month in FDA approvals. Here are the key approvals announced during the period (which runs from the third week in June through the third week in July):

NEW FDA APPROVALS

Manufacturer(s)	Product(s)
Quidel	510(k) clearance for Solana Bordetella Complete Assay run on Quidel Solana system for detecting and differentiating <i>Bordetella pertussis</i> and <i>Bordetella parapertussis</i> in nasopharyngeal swabs
Roche	Breakthrough Device designation for Elecsys beta-Amyloid (1-42) CSF, immunoassay for Alzheimer’s that measures beta-amyloid concentrations
Roche	Breakthrough Device designation for Elecsys Phospho-Tau (181P) CSF, immunoassay for Alzheimer’s that measures phospho-tau peptide concentrations
Roche	Clearance for expanded use of Elecsys BRAHMS PCT assay to aid in antibiotic therapy decision-making
Roche	Clearance for Elecsys CA 15-3 II assay on Elecsys and Cobas e immunoassay analyzers for determining CA 15-3 in human serum and plasma to help in management of breast cancer patients
LabCorp	Approval for UltraQual Multiplex PCR Assay for hepatitis C, HIV-1, HIV-2 and hepatitis B for screening donated blood plasma
Abbott	Clearance for Afinion HbA1c Dx assay to help diagnose diabetes mellitus and assess patient risk of developing disease
DiaSorin Molecular	Clearance extending sample type claims for its Simplexa HSV 1 & 2 Direct assay and expanding type of samples that can be tested to genital swabs and cutaneous and mucocutaneous swab samples

Manufacturer(s)	Product(s)
Ceres Nanosciences	Breakthrough Device designation for Nanotrap Lyme Antigen Test System which uses the firm's Nanotrap technology to detect Lyme infections
Hologic	Clearance for Aptima Combo 2 Assay, a nucleic acid test for detection and differentiation of ribosomal RNA from <i>Chlamydia trachomatis</i> or <i>Neisseria gonorrhoeae</i>
Bio-Rad	Clearance for BioPlex 2200 25-OH Vitamin D Kit, a multiplex flow competitive immunoassay to detect 25-hydroxyvitamin D in serum
Immco Diagnostics	Clearance for ImmuGlo HEp-2 Elite IFA indirect immunofluorescence test to detect anti-nuclear antibodies of IgG isotype in human serum
NeuMoDx Molecular	Clearance for NeuMoDx GBS Assay to Group B <i>streptococcus</i> DNA from enriched swabs from pregnant women
Ark Diagnostics	Clearance for Ark Fentanyl Assay immunoassay used with automated clinical chemistry analyzers to detect fentanyl in human urine at cutoff concentration of 1.0 2 ng/mL
Beckman Coulter Diagnostics	Clearance for Access hsTnl assay for use on Beckman Coulter's Access 2, Dxl, and other Access immunoassay systems to detect troponin I
PerkinElmer	Clearance for Euroimunn Crithidia luciliae test (CLIFT) and CLIFT sensitive immunofluorescence assays
Fujirebio Diagnostics	Clearance for received clearance for use of Lumipulse G BRAHMS PCT Assay for testing on Lumipulse G1200 immunoassay platform
Grifols	Clearance for Procleix Ultrio Elite combined screening test for HIV-1, hepatitis B and hepatitis C viruses + enabling HIV-2 detection
Grifols	Clearance for Procleix WNV test screening serum and plasma donations for West Nile virus run on Grifols' Procleix Panther system

New CE Marks & Global Certifications

Notable European CE certifications:

NEW CE CERTIFICATIONS IN EUROPE

Manufacturer(s)	Product(s)
Thermo Fisher Scientific	CE marking for the Phadia 200 benchtop instrument to test for allergies and autoimmunity conditions
PathoFinder	CE marking for RealAccurate TVMGres PCR Kit multiplex real-time PCR assay enabling simultaneous detection of <i>Trichomonas vaginalis</i> or <i>Mycoplasma genitalium</i> in urine and vaginal samples

Other international clearances announced in the past month:

Manufacturer(s)	Product(s)	Product(s)
Royal Philips	South Korea	Ministry of Food and Drug Safety approval of Philips IntelliSite Pathology Solution for use as a diagnostic tool
MGI (subsidiary of BGI)	China	China FDA medical device registration certificate for two next-generation sequencers, MGISEQ-2000 and MGISEQ-200

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

Thermo Fisher Scientific and Invitae were among the firms releasing multiple new products from the end of June through the third week of July. Here's a more complete rundown for the period.

NEWLY LAUNCHED PRODUCTS & SERVICES

Company(ies)	Product(s)
Sage Bionetworks	Agora platform, web-based tool enabling researchers to explore curated genomic analyses of Alzheimer's disease
Swift Biosciences	Early access to Swift 2S Turbo Library Kit
MNG Laboratories	Free addition of mitochondrial DNA sequencing and deletion analysis to MNG's Comprehensive Intellectual Disability/Autism NGS panel
AMS Biotechnology	CRISPR-Cas9 editing kits for gene knockout, gene knock-in and gene mutation applications
Biocartis	Automated Idylla MSI research-use-only assay evaluating microsatellite instability-status of a tumor from one slice of FFPE tumor tissue without need for a reference sample
Exosomics Siena	SelectEV-DNA for selective isolation of tumor-derived DNA from complex biofluids such as plasma or serum and isolation of circulating cell-free DNA
Exosomics Siena	SortEV-RNA for selective isolation of tumor-derived RNA from complex biofluids such as plasma or serum
Medical and Biological Laboratories (Japan)	MEBRIGHT NUDT15 kit for detecting genetic polymorphisms in NUDT15 (Nudix Hydrolase 15) gene, which can predict side effects of thiopurine drugs
Dante Labs	Whole GenomeZ whole-genome sequencing methodology
New England Biolabs	NEBNext Direct Custom Ready Panels for designing customized panels from library of pre-synthesized baits for about 850 genes associated with different diseases
Ultivue	UltiMapper portfolio of reagents for whole-slide protein biomarker spatial detection and analysis in tissue
Rheonix	Listeria PatternAlert assay for rapid identification of molecular patterns from Listeria strains
Devyser	Devyser Thalassemia kit for analyzing sequence variants in HBA1, HBA2 and HBB genes in human genomic DNA
WuXi NextCode	LifeCode.ai, a health databank that uses blockchain technology for secure management of health data
Thermo Fisher Scientific	Oncomine TCR Beta-SR Assay sequencing assay to characterize T-cell clonality in tumor microenvironment
Thermo Fisher Scientific	Thermo Scientific Orbitrap ID-X Tribrid Mass Spectrometer
Thermo Fisher Scientific	Invitrogen TaqMan kit for real-time RT-PCR
Thermo Fisher Scientific	SYBR Green Fast Advanced Cells-to-CT kit for real-time RT-PCR
Thermo Fisher Scientific	Ion AmpliSeq HD library preparation technology for customized NGS gene panels
Invitae	Invitae Comprehensive Carrier Screen for NGS-based analysis of 287 genes linked to serious genetic disorders and identification of disease-causing changes in genes analyzed

Company(ies)	Product(s)
Invitae	Invitae Broad Pan-Ethnic Carrier Screen assessing a smaller set of common disorders associated with 46 genes
Invitae	Invitae Pan-Ethnic Carrier Screen analyzing three genes associated with cystic fibrosis, spinal muscular atrophy and fragile X syndrome
10x Genomics	Single Cell Mouse Immune Profiling Solution for characterizing gene expression and paired receptor sequences of T cell and B cells in mouse models of disease
ArcticZymes	New proteinase enzyme
GenomeDx Biosciences + Pathnostics	Guidance test for patients with simple cystitis, recurrent, persistent or complicated urinary tract infections, prostatitis and interstitial cystitis
Twist Bioscience	High-throughput version of its Twist Human Core Exome Kit for NGS library preparation and target enrichment



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Industry Buzz: Criminal Charges May Spell the End for Theranos

Four years ago, Theranos was a \$10 billion company poised to turn a breakthrough blood testing technology into a diagnostics dynamo to the tune of \$70 billion in annual sales. Today, the company and its founding CEO, Elizabeth Holmes, are on the brink of financial and legal ruin.

The latest and most devastating blow came in May when a federal grand jury indicted Theranos CEO Elizabeth Holmes and former COO Sunny Balwani on nine counts of wire fraud and two counts of conspiracy, charges carrying a potential sentence of 20 years in prison, fines of \$250,000 per count and restitution.

According to prosecutors, “Holmes and Balwani used advertisements and solicitations to encourage and induce doctors and patients to use Theranos’ blood testing laboratory services,” all the while knowing that its touted finger-prick blood tests could not consistently produce accurate and reliable results.

Meanwhile, *The Wall Street Journal* reports that Theranos is headed for bankruptcy.

Five months ago, it appeared that Holmes and the company she founded in 2013 might be out of the woods when they settled stock fraud charges with the Securities and Exchange Commission. Now the prospects are far more grave. 



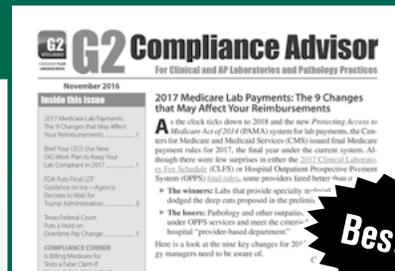
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