

HIGHLIGHTS

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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 diagnostic deal making picked up from the end of March through mid-April. Here's a quick overview of the activity and key deals made during the period.

Mergers & Acquisitions and Asset Sales

The M&A highlight was the announcement of the year's third nine-figure deal, namely Thermo Fisher Scientific's \$1.7 billion acquisition of Brammer Bio, a leader in viral vector manufacturing for gene and cell therapies. The deal, which is expected to close by the end of the second quarter of 2019, will

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FDA Watch: New Warning Letter May Signal Resurgence of LDT Enforcement Activity

After a couple of years of dormancy, the FDA laboratory developed test (LDT) enforcement volcano stirred on April 4, when the agency issued a [warning letter](#) to Inova Genomics Laboratory (Inova) for "illegally marketing" its MediMap genetic tests for predicting a patient's response to medication, specifically:

- ▶ MediMap Plus, which evaluates patient response to drugs treating, among other things, anesthesia, cancers, infections, attention-deficit/hyperactivity disorder, depression, anxiety and diabetes; and
- ▶ MediMap Baby, which analyzes a newborn's genes that influence response to 24 medications.

The FDA contends that Inova's website claimed that the tests provide "actionable and informational guidance" and that "[h]ealthcare providers can use these results confidently in

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■ **Diagnostic Deals:** A roundup of the key mergers, acquisitions, alliances, licenses and other strategic transactions from the past month, *from page 1*

strengthen Thermo Fisher’s presence in the pharma and biotech markets.

In addition to the other deals listed below, there was news regarding a previously announced acquisition. The UK government’s Competition and Markets Authority (CMA), a department in charge of promoting competition and reducing anti-competitive activities in the UK, has launched an investigation into Illumina’s planned acquisition of Pacific Biosciences.

This deal, announced last fall and initially scheduled to close mid-year, is valued at approximately \$1.2 billion. CMA is considering whether the acquisition will likely result “in a substantial lessening of competition within any market or markets in the United Kingdom for goods or services.” Illumina and PacBio haven’t commented on the CMA investigation.

Strategic Alliances

Among new alliances is a collaboration between Thermo Fisher Scientific and NX Prenatal aimed at developing clinical mass spectrometry-based proteomics tests to monitor fetal health *in utero* and assess the risk of adverse events like preterm birth and preeclampsia.

There were also two new alliances that involve Google. Genomenon, a genomic search company, is partnering with Google to offer genomic data technology on Google Cloud Platform. Parabricks, a provider of GPU-based bioinformatics software solutions for analyses of next-generation sequencing data, has entered into a similar arrangement to use Google Cloud Platform.

In addition to alliances noted in the chart:

- ▶ Qiagen announced that Lab Corp has joined its Day-One lab readiness program, which is designed to expedite the commercial launch of new drugs and *in vitro* diagnostic tests being developed by Qiagen and its partners once FDA approval is obtained; and
- ▶ Primerdesign, the molecular testing division of French diagnostics firm Novacyt, has extended its sepsis assay development contract with Seattle-based Immunexpress.

Here’s a summary of key diagnostic deals from late March through mid April:

MERGERS, ACQUISITIONS & ASSET SALES		
Acquiring Company	Target(s)	Deal Summary
Thermo Fisher Scientific	Brammer Bio	<ul style="list-style-type: none"> ■ Price: \$1.7 billion cash ■ Status: Expected to close Q2 2019 ■ Contract development and manufacturing organization for viral vectors used in gene and cell therapies to become part of TF's pharma services business within lab products and services segment

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MERGERS, ACQUISITIONS & ASSET SALES		
Acquiring Company	Target(s)	Deal Summary
Covance Drug Development (part of LabCorp)	Envigo	<ul style="list-style-type: none"> Price: \$485 million to be paid by LabCorp Status: Expected to close by June 2019 Covance to acquire Envigo's nonclinical research services business + Envigo's Research Models Services to buy LabCorp's Covance Research Products business
Yourgene Health	Elucigene	<ul style="list-style-type: none"> Price: £9.2 million (\$12.0 million), including £6.3 million in cash + £2.9 million in equity in stock (24.6 million new shares issued at 11.7 pence per) Status: Agreement to buy with no closing date announced Yourgene to fund acquisition boosting its presence in bolster its presence in noninvasive prenatal testing (NIPT) market by selling roughly 97.5 million new shares at 10.25 pence apiece to raise £10 million (which Yourgene board may increase to £11.8 million)
Precision Therapeutics	Helomics	<ul style="list-style-type: none"> Price: Precision issued 4 million shares of common stock and 3.5 million shares of Series D convertible preferred stock to Helomics capital stock holders after previously issuing them 1.1 million common shares In related exchange offer, Precision issued about 8.6 million additional shares of common stock to previous holders of Helomics promissory notes + about 14.2 million warrants at exercise price of \$1.00 per share + 600,000 warrants at an exercise price of \$.01 per share to previous warrant holders Status: Closed Helomics made Precision's wholly-owned sub Precision gets full access to Helomics' AI, precision medicine and integrated CRO assets
Sienna Cancer Diagnostics	Sevident	<ul style="list-style-type: none"> Price: \$300,000 cash + \$1 million worth of Sienna new ordinary shares + up to \$1.5 million in contingent future payments Status: Closed Sienna acquires Sevident's NET molecular capture platform for isolating and capturing molecular and cellular biomarkers from small clinical blood samples
Discovery Life Sciences (DSL) (resident associate company of HudsonAlpha Institute for Biotechnology)	HudsonAlpha's Genomic Services Lab (GSL)	<ul style="list-style-type: none"> Price: Undisclosed Status: Closed Form new division called HudsonAlpha Discovery combining GSL's expertise with DLS's global biospecimen and analytic services to provide clinically and scientifically annotated biospecimens, gene sequencing, bioinformatics and lab services to pharmaceutical, biotechnology, and diagnostics industries
Guardant Health	Bellwether Bio	<ul style="list-style-type: none"> Price: Undisclosed Status: Expected to close in April 2019 Bellwether Bio team to advance Guardant's LUNAR early detection product pipeline



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STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	Partner(s) 2+	Deal Summary
Thermo Fisher Scientific	NX Prenatal	<ul style="list-style-type: none"> Objective: Develop mass spectrometry-based proteomics assays for adverse pregnancy outcomes Dynamic: Combine NX's NeXosome technology with Thermo Fisher's liquid chromatography-mass spectrometry instrumentation to create tests to monitor fetal health in utero and assess risk of premature birth and other adverse outcomes
Genomenon	Google	<ul style="list-style-type: none"> Objective: Offer genomic data technology on Google Cloud Platform Dynamic: Genomenon's variants reference datasets to be available in Google's BigQuery data warehouse
Parabricks	Google	<ul style="list-style-type: none"> Objective: Offer genomic data technology on Google Cloud Platform Dynamic: Parabricks to launch new software suite for primary and secondary analysis of sequencing data on Google Cloud Platform Marketplace
Onegevity Health	Kirin Holdings + Mitsui	<ul style="list-style-type: none"> Objective: Launch Onegevity's GutBio assay + other products in Japan Dynamic: Licensing agreement which also provides for using Onegevity's AI-based platform to develop unique nutritional products
Genetic Technologies	Translational Genomics Research Institute	<ul style="list-style-type: none"> Objective: Commercialize Genetic Tech's polygenic risk tests in US Dynamic: Create joint US-based CLIA lab to offer tests, including Brevagenplus breast cancer risk assessment test + future oncology, cardiovascular disease and diabetes tests
FH Foundation	Invitae + Genome Medical	<ul style="list-style-type: none"> Objective: Improve diagnosis of HoFH (homozygous familial hypercholesterolemia) Dynamic: Launch new genetic testing program called FIND HoFH in which Invitae will provide free confirmatory genetic testing and Genome Medical free genetic counseling to individuals identified as needing HoFH evaluation
XCR Diagnostics	NeuMoDx Molecular	<ul style="list-style-type: none"> Objective: Develop assays for NeuMoDx's new PCR-based molecular systems Dynamic: Chemistry license under which XCR to develop and implement 3 assays for NeuMoDx's 96 and 288 systems, starting with multiplex test for Group A Streptococcus and Group C/G Streptococcus using latter's NeuDry reagents for 2019 launch in Europe
Evotec	Indivumed	<ul style="list-style-type: none"> Objective: Develop new precision therapeutics for colorectal cancer Dynamic: 2-year alliance. Indivumed to apply Evotec's PanHunter bioinformatics analysis platform and drug discovery technologies to a colorectal cancer cohort from its Indivumed database Evotec to pay Indivumed undisclosed amount for access to cohort and have responsibility for programs and platforms resulting from collaboration
CoaguSense	Point of Care Decision Support	<ul style="list-style-type: none"> Objective: Improve anticoagulant therapy healthcare workflow and decision-making Dynamic: Partnership leveraging PCDS' evidence-based anticoagulation software and CoaguSense's PT2 PT/INR Monitoring system
Somalogic	Janssen Research & Development	<ul style="list-style-type: none"> Objective: Discover and validate protein markers to predict, diagnose, monitor and treat rheumatoid arthritis, inflammatory bowel disease, lupus + cardiovascular and metabolic conditions Dynamic: Use Somalogic's SomaScan proteomics platform to analyze clinical samples for Janssen Latest example of Somalogic's business model switch from fee-for-service to collaboration
iCubate	Wondfo Biotech	<ul style="list-style-type: none"> Objective: Commercialize infectious disease molecular diagnostics in China Dynamic: Form new China joint venture called Wondfo-iCubate Biotech to develop assays using iCubate amplicon-rescued multiplex PCR (arm-PCR) technology

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	Partner(s) 2+	Deal Summary
VolitionRx	Fosun Long March Medical Science	<ul style="list-style-type: none"> Objective: Launch VolitionRx's NuQ blood-based cancer diagnostic platform in China Dynamic: Collaborate to test NuQ platform in 3 clinical studies in China in colorectal, lung and ovarian cancer Fosun Long March to help VolitionRx obtain and test blood samples for studies
22nd Century Group	KeyGene	<ul style="list-style-type: none"> Objective: Develop cannabis plants with enhanced properties for medical use Dynamic: Each firm to use its genomic, molecular genetics, trait discovery and breeding technologies to optimize the cannabinoid profiles of different cannabis varieties Firms to create a genetic database of cannabis lines + high-resolution map of cannabis genome
Centene	Washington University School of Medicine in St. Louis	<ul style="list-style-type: none"> Objective: Accelerate research of treatments for Alzheimer's, breast cancer, diabetes and obesity Dynamic: Centene to contribute up to \$100 million over 10 years to fund research at School's Personalized Medicine Initiative University to contribute research and biomedical capabilities, including CRISPR and other technologies, as well as scientists in microbiome, immunomodulatory therapies, cancer genomics, neurodegeneration, cellular reprogramming, chemical biology and informatics Products yielded by collaboration to be commercialized via a joint venture called the ARCH Personalized Medicine Initiative
Yikon Genomics	Center for Reproductive Health & Gynecology (CRHG)	<ul style="list-style-type: none"> Objective: Launch Yikon Genomics' non-invasive chromosomal screening assay for aneuploidy Dynamic: Firms to make test, which uses next-generation sequencing to screen embryos before implantation, available for commercial clinical services through a joint CLIA-certified genetics lab at CRHG
Myriad Genetics	AstraZeneca + Merck	<ul style="list-style-type: none"> Objective: Develop companion diagnostics for olaparip (Lynparza) Dynamic: Expansion of current collaboration (which began in 2007) to use Myriad's BRACAnalysis CDx to identify men with metastatic, castrate-resistant prostate cancer (mCRPC) + germline BRCA mutation likely to respond to the drug Myriad also to file supplementary premarket approval application with FDA for use of BRACAnalysis CDx as companion diagnostic for drug for that patient population
Genome Medical	Renown Health	<ul style="list-style-type: none"> Objective: Advance research into genetic causes of diseases Dynamic: Genome to provide genetic counseling and education services to study participants as part of Renown's Healthy Nevada Project
Shivom	Family Care Path	<ul style="list-style-type: none"> Objective: Provide Family Care Path's MyLegacy web-based clinical decision support application to Shivom customers Dynamic: Shivom to use its online app technology to make MyLegacy available to customers who want to schedule genomic counselling sessions
AiLife Diagnostics	BGI Americas	<ul style="list-style-type: none"> Objective: Develop clinical whole-genome sequencing test to diagnose genetic disorders Dynamic: Combine BGI's DNBseq NGS technology with AiLife's A-GPS, I-GPS, and D-GPS pipelines for NGS analysis, interpretation and reporting

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	Partner(s) 2+	Deal Summary
Cellgen Diagnostics	Genomic Testing Cooperative	<ul style="list-style-type: none"> Objective: Offer companion diagnostic development services to cancer immunotherapy developers Dynamic: Combine Cellgen's cartridge assay-based molecular diagnostics platform with GTC's biomarker discovery technologies to create new service for pharma customers for biomarker discovery and validation + in vitro diagnostic companion assay development
Chembio Diagnostics	Perseus Science Group	<ul style="list-style-type: none"> Objective: Develop diagnostic test for concussion Dynamic: Perseus to provide undisclosed funding amount to Chembio to develop a quantitative point-of-care test for concussion that combines Perseus' concussion biomarker with Chembio's DPP platform
Bluejay Diagnostics	US Naval Medical Research Center	<ul style="list-style-type: none"> Objective: Develop non-invasive point-of-care test for early-stage detection of Lyme disease Dynamic: Two-year cooperative research and development agreement to study antigens associated with various pathogens and identify the most immunoreactive antigen + use information to develop rapid test for detecting pathogen antigens in biofluids, including serum and urine
NanoString	Leica Biosystems	<ul style="list-style-type: none"> Objective: Create research workflow integrating NanoString's GeoMx Digital Spatial Profiling (DSP) instrument with Leica's Bond RX autostainer Dynamic: Comarketing agreement allowing Leica to promote GeoMx technology to its Bond RX customers, and NanoString will to promote the Bond RX system to its GeoMx DSP customers
NanoString	Bio-Techne	<ul style="list-style-type: none"> Objective: Create a workflow for spatial genomics research Dynamic: Combine Bio-Techne's RNAscope reagent portfolio with NanoString's GeoMx RNA assays and digital spatial profiling instrument NanoString also to provide RNAscope research services via its GeoMx DSP Technology Access Program
LifeMap Sciences	Genomenon	<ul style="list-style-type: none"> Objective: Enable researchers using GeneCards to more easily identify relevant literature associated with genes, diseases and variants Dynamic: Integrate Genomenon's Mastermind Genomic Search Engine into LifeMap's GeneCards knowledge base
Circuit Clinical	University of Buffalo	<ul style="list-style-type: none"> Objective: Circuit Clinical to leverage UB's genomics and biorepository resources for its drug-discovery services Dynamic: Partnership allowing Circuit Clinical to collect, store and process blood, tissue and bodily fluids through UB biorepository for genomic sequencing and microbiome studies in a value-sharing model
Definiens	Ultivue	<ul style="list-style-type: none"> Objective: Develop immuno-oncology research offerings that combine each firm's multiplexed immunofluorescence (IF) immunohistochemistry and digital image analysis technologies Dynamic: First products to be based on UltiMapper kit panels for PD-1 and PD-L1 Plan is to expand to a novel 8-plex IF immuno-oncology panel

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	Partner(s) 2+	Deal Summary
Covance (owned by LabCorp)	Mission Bio	<ul style="list-style-type: none"> Objective: Offer single-cell DNA analysis services to Covance biopharm customers on Mission Bio's Tapestri single-cell platform Dynamic: Firms also plan to evaluate platform for development of companion diagnostics
ArcherDx	University College London (UCL) + Francis Crick Institute	<ul style="list-style-type: none"> Objective: Lung cancer research Dynamic: Use ArcherDx's anchored multiplex PCR (AMP) technology to detect disease recurrence in lung cancer patients from cell-free circulating tumor DNA as part of UCL-sponsored Tracking Lung Cancer Evolution Through Treatment (TRACERx) study
Mayo Clinic Laboratories	Breath Diagnostics	<ul style="list-style-type: none"> Objective: Develop tests that use patient breath samples to identify biomarkers that can predict various diseases Dynamic: Build test on Breath Diagnostics' OneBreath microreactor technology to capture specific cancer biomarkers from a single breath and provide results in less than 24 hours
Group K Diagnostics	US Centers for Disease Control	<ul style="list-style-type: none"> Objective: Evaluate prototype reverse transcriptase loop-mediated isothermal amplification (RT-LAMP) assay for point of care detection of Zika virus (ZIKV) RNA Dynamic: Group K contributing its expertise in microfluidic point-of-care testing + logistical demands in resource-limited areas
Horizon Discovery Group	St. George's University Hospital (London) + European Molecular Genetics Quality Network (EMQN)	<ul style="list-style-type: none"> Objective: Develop reference material for non-invasive prenatal testing (NIPT) Dynamic: Horizon to provide expertise in development of genetically defined, cell line-derived reference material St. George's to provide clinical samples EMQN to run comprehensive validation study using its global network of labs performing NIPT
DISTRIBUTION, SALES & MARKETING AGREEMENTS		
Property Owner	Distributor	Deal Summary
Todos Medical	Orot+	<ul style="list-style-type: none"> Products: Todos' TM-B2 breast cancer screening blood tests Territory: Romania + Austria Exclusive
Oncimmune	Sabartech	<ul style="list-style-type: none"> Products: Oncimmune's EarlyCDT-Lung lung cancer test Territory: Portugal Sabartech made exclusive distributor with minimum sales commitment of £700,000 (\$911,619) over 5 years Firms also extend Sabartech's distributorship agreement in Spain from 3 to 5 years
Curetis	A. Menarini Diagnostics	<ul style="list-style-type: none"> Strategic long-term deal making Menarini exclusive distributor of Curetis products in Germany, France, Benelux, UK, Switzerland, markets in which Curetis previously sold directly Menarini also made exclusive distributor in Italy, Spain, Portugal, in which Curetis sold thru local company distributors Menarini also to commercialize Curetis Unyvero cartridge-based multiplex PCR molecular diagnostics platform in Sweden

LICENSES		
Licensor	Licensee	Deal Summary
ArcDia International	Xinhua Healthcare Industry	<ul style="list-style-type: none"> Property: ArcDia's MariPOC biochemical testing platform Exclusive deal limited to China under which ArcDia also to provide Xinhua with research and development services
Banyan Biomarkers	Abbott	<ul style="list-style-type: none"> Property: Banyan's traumatic brain injury (TBI) blood biomarkers, including ubiquitin carboxyl terminal hydrolase-L1 and glial fibrillary acidic protein Non-exclusive
SUPPLY, SERVICE & TESTING AGREEMENTS		
Supplier/Service	Client/User	Deal Summary
Abcam	NanoString	<ul style="list-style-type: none"> Abcam to provide NanoString antibodies for use with its GeoMx Digital Spatial Profiler (DSP) platform
Quest Diagnostics	Regional Medical Center (Orangeburg, SC)	<ul style="list-style-type: none"> Quest to provide full lab management services, including lab equipment, supplies and procurement processes
NEW CLINICAL STUDIES		
DX Partner	Other Partner(s)	Deal Summary
DNAexus	Sutter Health network + University Pittsburgh Medical Center (UPMC)	<ul style="list-style-type: none"> Multiple sclerosis (MS) research study in which scientists at the Sutter Health Center for Precision Medicine scientists will add clinico-genomic data from over 3,000 patients to the DNAexus Apollo platform, and the Genome Center at UPMC will generate clinical-grade genomic data from samples from program participants
Natera	Amal Therapeutics	<ul style="list-style-type: none"> Clinical trial to test Signatera, Natera's bespoke circulating tumor DNA assay to assess treatment response in late-stage colorectal cancer patients as well as Amal's cancer vaccine, ATP128, in combination with a PD-1 inhibitor in patients with stage IV colorectal cancer 

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

Qiagen was the most active firm of the period with a trio of new product launches, including the US launch of Therascreen FGFR RGQ RT-PCR Kit as a companion diagnostic for Janssen Pharmaceutical's metastatic bladder cancer drug erdafitinib following FDA approval of the test. Among the more notable launches was GenePrism:Actionable Insights, the result of a collaboration between PerkinElmer and Helix. The firms touted the new genetic screening test enabling users to assess their risk for underlying diseases as “the most comprehensive clinical grade DNA sequencing and interpretation” test currently on the market.”

Here's a summary of all the key product launches from late March to mid-April 2019:

NEWLY LAUNCHED PRODUCTS & SERVICES

Company(ies)	Product(s)/Service(s)
PerkinElmer and Helix	GenePrism:Actionable Insights, a genetic screening test
Fluidigm	Maxpar Direct Immune Profiling System for rapidly quantifying 37 different immune cell populations from human peripheral blood mononuclear cells and whole blood
Ares Genetics (Curetis subsidiary)	NGS service based on its AresUPA Universal Pathogenome Assay to launch later this year
Qiagen	US launch of Therascreen FGFR RGQ RT-PCR Kit as companion diagnostic for Janssen Pharmaceutical's metastatic bladder cancer drug erdafitinib (Balversa) to run on Qiagen's Rotor-Gene Q MDx
Qiagen	exoRNeasy Midi and Maxi Kits for isolating exosomes and other extracellular vesicles from urine and other samples
Qiagen	miRNeasy 96 Advanced QiaCube HT Kit for automated purification of total RNA, including miRNA, from serum and plasma samples
Centogene	CentoMetabolic panel, a first-line test for rare genetic metabolic diseases
PetaGene	PetaSuite Protect encryption and access-management system for genomic data
Enpicom	IGX, short for ImmunoGenomiX immune sequencing data analysis platform
Quantabio	Qscript lyo 1-step, lyophilized single-reaction reagent for highly sensitive and reproducible RT-qPCR RNA uses
Fabric Genomics	Fabric Hereditary Panels with ACE (AI Classification Engine) software for variant interpretation and clinical reporting
Emedgene	Addition of automated evidence retrieval to its genetic interpretation platform
Progenity	Resura prenatal test for monogenic disease, a customizable, noninvasive prenatal test (NIPT) for single-gene disorders
Agilent Technologies	4150 TapeStation system for analyzing quality of RNA and DNA samples
BGI Americas	Oseq Hereditary Cancer Panel (HGP), assay that to identify tumor biomarkers for 17 cancer types and support clinical trials of anti-cancer drugs
Canopy Biosciences	RareSeq error corrected sequencing service
GenScript	New single-stranded DNA (ssDNA) service giving researchers access to its ssDNA for CRISPR-based gene insertion
Congenica	On-premises installation option for its Sapiientia genome analysis platform that was previously available only as a cloud product

Company(ies)	Product(s)/Service(s)
RareCyte	CyteFinder II and CyteFinder II HT instruments, next-generation versions of its CyteFinder instruments for multi-omic liquid biopsy and tissue research
BC Platforms	Incorporation of ontology browser and data visualization dashboard to its BC Insight data management platform
HTG Molecular Diagnostics	HTG EdgeSeq Mouse mRNA Tumor Response Panel
Arima Genomics	Arima-HiC sample preparation kit 

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■ FDA Watch: New Warning Letter May Signal Resurgence of LDT Enforcement Activity, from page 1

making treatment decisions.” In its [press release](#) announcing the warning letter, the FDA commented that it “is unaware of any data establishing that Inova’s test can help patients or health care providers make appropriate treatment decisions for the listed drug.” The FDA stated that this warning letter “reflects the agency’s commitment to monitor the pharmacogenetics test landscape and take action when appropriate to address a significant public health risk.”

The Director of the FDA’s Center for Devices and Radiological Health explained that the FDA is “particularly concerned about pharmacogenetic tests that claim to predict patients’ responses to specific medications where such claims have not been established and are not described in the drug labeling and continue to warn patients and health care professionals that they should not rely on these tests for treatment decisions.”

The 2 takeaways from the warning letter:

1. The FDA can and will take action against LDTs, particularly ones being marketed directly to consumers; and
2. If the physician who orders the test is affiliated with the lab, the physician order may not be enough to keep the agency from suspecting direct-to-consumer marketing.

Extension of 510(k) Pathway Proposal

The month’s other key development was the FDA’s announced decision to extend for 30 days the comment period for [guidance](#) on changing the Section 510(k) premarket review process for new devices and diagnostic tests. The new comment deadline is May 22, 2019. (For an analysis of the proposal, see [Lab Industry Report \(LIR\), February 2019](#)).

New FDA Approvals

Here's a look at the key FDA approvals announced from late March to mid-April, 2019:

NEW FDA APPROVALS

Manufacturer(s)	Product(s)
Agilent Technologies	Clearance for PD-L1 IHC 22C3 pharmDx assay as companion diagnostic test for Merck's anti-PD1 immunotherapy pembrolizumab (Keytruda) for non-small cell lung cancer (NSCLC) expanded to include identifying patients with stage III NSCLC who aren't candidates for surgical resection or definitive chemoradiation, or patients with metastatic NSCLC whose tumors express a PD-L1 Tumor Proportion Score \geq 1%, and who are eligible for first-line treatment with Keytruda
GenMark Diagnostics	510(k) clearance for ePlex Blood Culture Identification Gram-Negative (BCID-GN) panel assay to detect gram-negative bacteria in blood cultures
Qiagen	Clearance for Therascreen FGFR RGQ RT-PCR Kit as companion diagnostic for Janssen Pharmaceutical's metastatic bladder cancer drug erdafitinib (Balversa)
Bio-Rad Laboratories	Clearance for IH-500 automated random access system for blood typing and screening
Bio-Rad Laboratories	Clearance for Lyme Total Assay for Lyme disease run on firm's BioPlex 2200 System
Ortho Clinical Diagnostics	Clearance for Vitros XT MicroSlides multitest technology, which enables labs to run two tests simultaneously on one MicroSlide
AggreDyne	Clearance for AggreGuide A-100 ADP Assay, cartridge measuring effect of antiplatelet medications targeting P2Y12 platelet receptor
CoaguSense	510(k) clearance for Coag-Sense PT2 meter for professional use in CLIA-waived setting and for self-testing by patients at home
Siemens	Clearance for Dimension Vista High-Sensitivity Troponin I assay for measuring cardiac troponin I in plasma using firm's Dimension Vista system
Beckman Coulter	510(k) clearance for Early Sepsis Indicator hematologic biomarker
Beckman Coulter	510(k) clearance for DxH 520 hematology analyzer, which is designed for clinics, MD offices and other low-volume labs

New CE Marks & Global Certifications

Notable European CE certifications during the period:

NEW CE CERTIFICATIONS IN EUROPE

Manufacturer(s)	Product(s)
Hologic	CE-IVD marking for ThinPrep Genesis processor that prepares slides for cytology and aliquot samples for molecular testing

Manufacturer(s)	Product(s)
Ortho Clinical Diagnostics	CE marking for Vitros High Sensitivity Troponin I assay to rapidly identify patients suffering from heart attacks and low-risk patients who may be safely discharged from hospital
Sophia Genetics	CE-IVD marking for Solid Tumor Solution (STS) molecular diagnostic application
GenePOC	CE marking for Carba assay for carbapenemase-producing organisms
Bluejay Diagnostics	CE marking for Allereye Tear Total IgE point-of-care test for allergic conjunctivitis
Becton Dickinson	CE-IVD marking for BD FACSDuet automated sample preparation system for flow cytometry

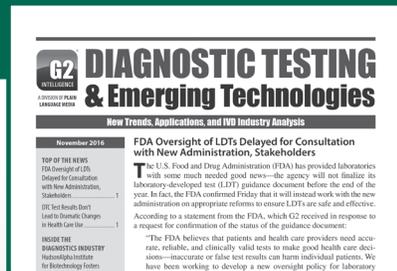
Other international clearances announced during the period:

Manufacturer(s)	Country(ies)	Product(s)
Cytek Biosciences	China	National Medical Products Administration (NMPA) approval for DXP Athena 13-color flow cytometer
Chembio Diagnostics	Brazil	Agência Nacional de Vigilância Sanitária (ANVISA) approval for DPP Zika/Dengue/Chikungunya point-of-care system



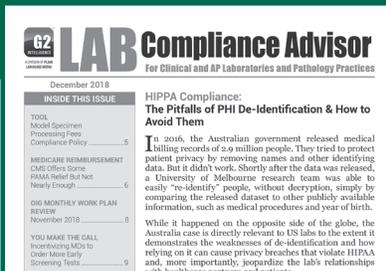
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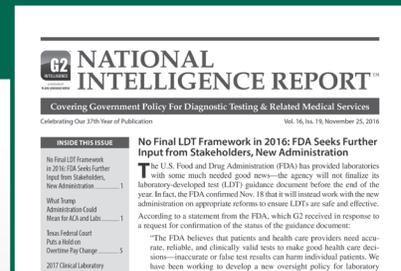
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