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LABORATORY

INDUSTRY REPORT™

Vol. 18, Iss. 7
July 2018



HIGHLIGHTS

FDA Watch:

Agency Offers a Modicum of Relief on DTC Marketing of Genetic Tests 2

The Dx Pipeline:

A Roundup of the Month's Key New Product Launches 11

Top of the News:

ANDE Rapid DNA Platform First to Win FBI Approval 12

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Upcoming Events

Lab Institute 2018

Surviving Disruption: Rethinking Business Models, Technologies, and Competitive Strategies in a Changing Lab Market

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.lableadershipsommits.com

Industry Buzz: LabCorp and Quest Swept Up in Insurance Contract Partner Swap

Can you imagine Scarlett and Rhett swapping partners with Romeo and Juliet? Something like the laboratory industry equivalent of that scenario took place on May 25 when two of the nation's largest private health insurers announced they were dropping their own longstanding lab contractor partner in favor of the other's.

UnitedHealthcare & LabCorp

Effective Jan. 1, 2019, Laboratory Corporation of America will no longer be UnitedHealthcare's exclusive provider of laboratory services. It's not a divorce. LabCorp will remain part of the UnitedHealthcare network. But it will now have to share those 48+ million members with arch rival Quest Diagnostics as a fellow preferred provider. Previously, Quest provided lab services to UnitedHealthcare members in a few select markets via its AmeriPath anatomic pathology business. Securing a piece of

Continued on page 2

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

Mid-May to mid-June was the busiest period of the year for diagnostic deal making in terms of both volume and magnitude. Here is a look at the highlights.

M&A

Dollar value-wise, the biggest lab M&A deal of 2018 to date came down on June 19 when Roche announced plans to acquire the remainder of Foundation Medicine for \$2.4 billion. Roche had previously acquired 57% of the Cambridge, Mass.-based genomic cancer analysis diagnostics firm via a 2015 tender offer. Under the new deal, Roche will buy the remaining shares at \$137 per share in cash, a premium of:

Continued on page 5

■ Industry Buzz: LabCorp and Quest Swept Up in Insurance Contract Partner Swap, *from page 1*

the UnitedHealthcare pie means that Quest will be in network with “90% of insured lives nationally” across all its payor relationships, noted Quest CEO Steve Rusckowski.

Aetna & Quest

The yin to this yang is the parallel announcement that Aetna has decided to end its lab services exclusive with Quest. Come Jan. 1, LabCorp will also gain the status of Aetna national preferred lab services provider with access to the Hartford-based insurer’s network of 20+ million strong. Quest will also remain an Aetna preferred provider but will no longer hold a monopoly on that status. Quest’s relationship with Aetna “remains strong and unchanged,” according to a company spokesperson.

LIR

Glenn S. Demby,
Editor

Lori Solomon,
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Laboratory Industry Report (ISSN 1060-5118) is published by G2 Intelligence, Plain Language Media, LLLP, 15 Shaw Street, New London, CT, 06320.
Phone: 888-729-2315
Fax: 855-649-1623
Web site: www.G2Intelligence.com.

FDA Watch: Agency Offers a Modicum of Relief on DTC Marketing of Genetic Tests

Last November, the FDA raised eyebrows with a [notice for public comment](#) proposing to make it easier to bring new genetic health risk (GHR) assessment tests to market. The message to GHR test manufacturers: Once you get first time premarketing authorization, you can sell new GHR tests directly to consumers (DTC) without undergoing additional review. Earlier this month, the agency finalized the proposal.

The New DTC Genetic Tests Exemption

The [June 5 notice](#), (which also says that not even premarket notification is necessary for certain class II (moderate risk) GHR assessment *devices*) is the latest example of the FDA’s new “flexible” regulatory approach to genetic risk tests. “As consumer interest in genetic risk information grows, opportunities are also expanding for the detection of additional genetic conditions and diseases that can help inform people of their medical risks,” according to the statement.

While acknowledging that these tests pose risks “especially if they provide consumers with incorrect or misleading information that may be used to make health choices without the advice of a medical professional,” the agency insisted that one-time premarket authorization would be enough to manage the problems of false negatives and false positives. And, of course, test manufacturers would still be on the hook for making false claims in their DTC advertising.

Doesn’t Apply to GHR Tests Used for Treatment Decisions

The notice also makes it clear that the new exemption does not apply to GHR tests used to inform treatment decisions. The four types of tests that cannot be commercialized even with prior premarket approval include:

1. Prenatal testing;
2. Cancer predisposition testing;

3. Pharmacogenomics testing; and
4. Genetic diagnosis of deterministic autosomal dominant variants.

The not-for-treatment-decision limitations are consistent with previous FDA policy. Thus, for example, earlier this year, when the FDA granted first ever premarket authorization to 10 GHR tests from consumer genomics firm 23andMe, it attached strings in the form of “caveats” or controls restricting DTC marketing of GHR tests used to inform treatment decisions, such as hereditary cancer tests analyzing BRCA1 and BRCA2 genetic mutations that may influence women to decide whether to have a prophylactic mastectomy. (For more details, see *NIR*, April 3, 2018.)

New FDA Approvals

Here’s a rundown of the key new FDA approvals announced from mid-May through the third week in June:

NEW FDA APPROVALS

Manufacturer(s)	Product(s)
AutoGenomics	Breakthrough device designation for Infiniti Neural Response Panel, genomic test measuring risk for opioid dependency, for physician use as an aid in prescribing pain medication
Grifols	Clearance for Procleix Ultrio Elite, a combined screening test run on Grifols' Procleix Panther system for HIV-1, hepatitis B, hepatitis C viruses and detection of HIV-2
Grifols	Clearance for Procleix Panther nucleic acid test blood screening platform
Abbott Laboratories	Clearance for clinical chemistry magnesium assay used for quantitation of magnesium in human serum or plasma on Abbott's Architect c8000 system
Alere	Clearance for Alere i Strep A 2 molecular test for qualitative detection of Streptococcus pyogenes or Group A Streptococcus bacterial nucleic acid in throat swab specimens
Alere	Clearance for Afinion HbA1c Dx used for measuring glycated hemoglobin or percentage of hemoglobin A1c in human venous and capillary whole blood
PerkinElmer	Clearance for C. luciliae immunofluorescence test (CLIFT) lupus diagnostics (already cleared in Europe)
Bühlmann Laboratories	Clearance for fCal ELISA assay to diagnose Crohn's disease and ulcerative colitis
Gold Standard Diagnostics	Clearance for <i>Borrelia burgdorferi</i> IgG/IgM ELISA assay for use as initial screen in the two-step testing process recommended by the US Centers for Disease Control and Prevention for detecting antibodies against B. burgdorferi bacteria
Agilent Technologies	Clearance for expanded use of Dako PD-L1 IHC 22C3 pharmDx assay as companion diagnostic test for Keytruda for cervical cancer
Fujirebio Diagnostics	Clearance for expanded use of Lumipulse G BRAHMS PCT Assay for testing on Lumipulse G1200 immunoassay platform
Micronics (subsidiary of Sony)	Clearance for PanNAT microfluidic molecular diagnostics system and related test for Shiga toxin-producing <i>Escherichia coli</i> (STEC)
T2 Biosystems	Clearance for T2Bacteria Panel to detect species of bacteria in whole blood samples from patients with potential bloodstream infections
Roche Ventana Medical Systems	Clearance for Ventana CD30 (Ber-H2) assay for qualitative detection of CD30 protein in tissue stained with Ventana BenchMark Ultra instrument and OptiView DAB IHC Detection Kit
Sekisui Medical	Clearance for chromogenic test that includes CP3000 Coagulation Analyzer, Coagpia AT Reagent, Coagpia Calibrator and Coagpia Control Set

During the period, the following FDA CLIA waiver was announced:

NEW FDA CLIA WAIVERS

Manufacturer(s)	Product(s)
Cepheid	CLIA waiver for Xpert Xpress Strep A test to detect Group A Strep infection

New CE Marks & Global Certifications

Notable European CE certifications:

NEW CE CERTIFICATIONS

Manufacturer(s)	Product(s)
BioGx	CE marking for six tests for various meningitis infections and antibiotic-resistant organisms designed to run on Becton Dickinson's PCR-based BD Max platform
IncellDx	CE marking for flow cytometry-based test for human papillomavirus

Other international clearances announced in the past month:

Manufacturer(s)	Product(s)	Product(s)
Hologic	Canada	HealthCanada approval of Panther Fusion system and assays for respiratory virus infections
Vela Diagnostics	China	China FDA approval of Sentosa SX, cell-free DNA kit
Genetic Signatures	Australia	Australian Therapeutic Goods Administration registration to sell Extended Spectrum Beta-Lactamase and Carbapenemase Producing Organisms Detection Kit for detecting antibiotic-resistant pathogens



LAB LEADERSHIP SUMMITS

Lab Billing, Payments & Collections Summit

Practical, "How-to" Strategies to Boost Cash Flow, Increase Lab Profitability & Reduce Compliance Risk

Denver, CO, August 3, 2018

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What You Need to Know and Do to Get Ready for the New 2019 Clinical Lab Fee Schedule

Atlanta, GA, November, 2018

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■ Diagnostic Deals, from page 1

- ▶ 29% over Foundation's June 18 closing price;
- ▶ 47% over its 30-day volume weighted share price; and
- ▶ 68% over its 90-day volume weighted average share price.

While the two firms have been close collaborators, the acquisition enables Roche to further leverage Foundation's molecular analysis and genomic profiling assets to enhance its personalized healthcare strategy. The deal, which is expected to close before the end of 2018, is actually being treated as a merger under which Foundation will retain its autonomy.

Also making a splash was Myriad Genetics which announced its agreement to acquire women's health molecular diagnostics firm Counsyl for \$375 million in cash and common stock. Myriad plans to merge Counsyl's reproductive health products, including the Foresight test, with its existing preventive care business to form a new unit called Myriad Women's Health which will target OB-Gyns and reproductive healthcare providers. Myriad will also combine its women's health sales force of approximately 225 reps with Counsyl's 80 sales pros.

Meanwhile, Agilent Technologies remains highly aggressive in the M&A space completing its \$250 million purchase of Advanced Analytical Technologies and announcing two new acquisitions: Korean scientific instruments distributor Young In Scientific and chemical standards provider Ultra Scientific, both for undisclosed amounts.

One deal that did not come off was the merger between Rosetta Genomics and Genoptix which was supposed to happen on May 27. What went wrong? On May 30, Rosetta claimed that Genoptix refused to provide the required assurances of completing the transaction due to an undisclosed "material adverse effect" affecting Rosetta, as well as breaches of representations and warranties and said it would file for bankruptcy if the deal cratered. Sure enough, the deal cratered and Rosetta filed for Chapter 7 the very next day.

Strategic Alliances

Alliance making was also dynamic during the period. Four weeks before word of the Roche merger came down, Foundation Medicine announced a new collaboration with Merck to develop companion diagnostic tests for use with Merck's Keytruda anti-PD-1 immunotherapy drug. Meanwhile, Roche announced a pair of deals with pharmaceutical companies to develop companion diagnostics, including:

- ▶ A new agreement to develop immunohistochemistry CDx assays for Five Prime Therapeutics' investigational drugs and antibodies; and
- ▶ Extension of its current CDx oncology drug development agreement with Pierre Fabre.

On May 24, Qiagen made news by announcing termination of an NGS-based assay commercialization initiative with HTG Molecular Diagnostics—the first of a larger multi-project development agreement between the two firms, which remains intact despite failure of the maiden effort. A week later, Qia-

gen and Freenome inked a deal to combine the latter's AI genomics platform with the former's molecular analysis technology to develop NGS-based immune-oncology companion diagnostics for pharmaceutical companies.

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

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 Roche, which owns 57% of Foundation, to pay 29% premium of \$137 per share to acquire remaining shares Deal furthers Roche's personalized healthcare strategy since molecular analysis and genomic profiling enable development of new cancer treatments
Agilent Technologies	Advanced Analytical Technologies	<ul style="list-style-type: none"> Price: \$250 million cash Status: Closed AA's 109 employees to join Agilent as part of new biomolecular analysis division within Agilent's diagnostics and genomics group
Agilent Technologies	Young In Scientific	<ul style="list-style-type: none"> Price: Undisclosed Status: Agreement to acquire with no closing date announced Agilent acquires leading South Korea distributor of analytical and scientific instruments and long-time distributor of its own instruments and services Agilent products and services in South Korea formerly sold through YI Scientific to be integrated directly into Agilent's sales and service portfolio
Agilent Technologies	Ultra Scientific	<ul style="list-style-type: none"> Price: Undisclosed Status: Agreement to acquire with no announced closing date Agilent acquires provider of chemical standards and certified reference materials
Laboratory Corporation of America	Sciformix	<ul style="list-style-type: none"> Price: Undisclosed Status: Closed Sciformix, which provides pharmacovigilance and regulatory solutions for biopharm and medical device firms, to become part of LabCorp's Covance drug development business
Bruker	Sierra Sensors	<ul style="list-style-type: none"> Price: Undisclosed Status: Closed Bruker acquires German developer and manufacturer of analytical biosensors based on Surface Plasmon Resonance detection
Myriad Genetics	Counsyl	<ul style="list-style-type: none"> Price: \$375 million cash and common stock Status: No closing date announced Acquisition of molecular diagnostics firm bolsters Myriad's position in the women's health market
CFD Research Corporation	iXpressGenes	<ul style="list-style-type: none"> Price: Undisclosed Status: Closed CFDRC acquires iXG's microbiome-based drug discovery division, including high-throughput antimicrobial discovery platform, EMAD (extremophilic microbiome antimicrobial discovery) and key associated personnel
Inspirata	Caradigm (owned by GE Healthcare)	<ul style="list-style-type: none"> Price: Undisclosed Status: Closed Acquisition of healthcare analytics firm and its Caradigm Intelligence Platform enables Inspirata to step up development of its Cancer Information Data Trust platform
Renova Health	Tennessee rural hospital owned by Community Health Systems	<ul style="list-style-type: none"> Price: \$1 million cash Status: Closed Acquisition of 85-bed hospital gets lab company which is struggling after insurers stopped covering its toxicology tests into the hospital market
PerkinElmer	Shanghai Spectrum Instruments	<ul style="list-style-type: none"> Price: Undisclosed Status: Closed Acquisition of analytical instruments maker in China complements PerkinElmer's atomic spectroscopy business and position in Chinese environmental, industrial and food markets

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	Partner 2	Deal Summary
Foundation Medicine	Merck	<ul style="list-style-type: none"> Objective: Develop companion diagnostic tests for use with Merck's anti-PD-1 immunotherapy drug Keytruda Dynamic: Firms to develop pan-cancer CDx to measure microsatellite instability (MSI), CDx tests for tumor mutational burden and other novel biomarkers of response
Illumina	Foundation Medicine	<ul style="list-style-type: none"> Objective: Extend and expand current supply and service agreement Dynamic: Illumina to supply Foundation and its German sub with sequencers, reagents and instrument maintenance and repair services Foundation Medicine agrees to buy a specific amount of reagents every six months Sequencers and service contract prices to be based on Illumina list prices Reagents and consumables prices fixed for set time period
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
Laboratory Corporation of America	Unilabs	<ul style="list-style-type: none"> Objective: Create global network to develop and commercialize companion diagnostics Dynamic: Firms to globally harmonize processes to simplify technical, regulatory and clinical complexities initially focusing on commercial availability of assays developed by LabCorp via its Covance business
Roche	Five Prime Therapeutics	<ul style="list-style-type: none"> Objective: Develop immunohistochemistry companion diagnostic assays for use with Five Prime's investigational drugs and antibodies Dynamic: Develop, validate and commercialize tissue-based IHC CDx assay to identify patients who can benefit from drugs/antibodies
Roche	Pierre Fabre	<ul style="list-style-type: none"> Objective: Extend companion diagnostic agreement for Fabre's oncology drug candidate Dynamic: Original deal for Roche to develop prototype assay to be used as CDx for W0101, Fabre's antibody candidate drug targeting insulin-like growth factor 1 receptor extended to retrospective determination of IGF-1R expression in international Phase I/ II clinical study patients
Natera	Institut Jules Bordet (Belgium)	<ul style="list-style-type: none"> Objective: Collaborate on breast cancer research project using Natera's Signatera circulating tumor DNA assay Dynamic: Natera to analyze roughly 300 plasma samples from 80 patients diagnosed with non-metastatic breast cancer who were treated with chemosurgery followed by surgery. Researchers to use Signatera to evaluate molecular response and minimal residual disease, compare assay with standard recurrence monitoring and serial imaging, and correlate Signatera with clinical outcomes
Genetic Technologies	Swisstec	<ul style="list-style-type: none"> Objective: Develop service platform using blockchain technology for medical services and personalized health management Dynamic: Platform to be developed via new joint venture company which will provide predictive genomic screening, radiology services, clinical consultations and procedures across multiple disciplines starting in southeast Asia Each firm to own 50% of JV company
Leo Pharma	FibroTx	<ul style="list-style-type: none"> Assess disease severity and monitor treatment effects in atopic dermatitis patients using non-invasive skin test technology developed by FibroTx
Prevention Genetics	Inozyme Pharma	<ul style="list-style-type: none"> Objective: Launch no-cost genetic testing program to improve detection of rare calcification disorders for which Inozyme is developing treatments Dynamic: Program to offer free testing to individuals with a suspect family history for mutations in ENPP1 and ABCC6 genes
Ambry Genetics	Akcea Therapeutics (affiliate of Ionis Pharmaceuticals)	<ul style="list-style-type: none"> Objective: Launch new genetic testing program to provide no-cost analyses and genetic counseling to people with suspected hereditary ATTR (hATTR) amyloidosis Dynamic: Under program (called hATTR Compass), Ambry to test individuals for genes that cause hereditary polyneuropathies as well as genes associated with hereditary cardiomyopathies Genetic counseling to be provided via partnership with virtual care company PWNHealth
Prematha Health	Coastal Genomics	<ul style="list-style-type: none"> Objective: Develop clinical DNA sequencing test technologies Dynamic: Coastal to provide customized solution to Prematha for use in DNA sequencing
Lucence Diagnostics	Quest Laboratories (Singapore)	<ul style="list-style-type: none"> Objective: Offer cancer detection blood tests in region Dynamic: Quest to provide the tests based on Lucence's liquid biopsy technology
Genomenon	Fluidigm	<ul style="list-style-type: none"> Objective: Offer evidence-based genomic panel design services for translational and clinical disease researchers Dynamic: Co-marketing deal leveraging Fluidigm's automated microfluidic systems and Genomenon's Mastermind Panel Design Service for identifying disease-specific biomarkers

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	Partner 2	Deal Summary
Genomenon	Swift Biosciences	<ul style="list-style-type: none"> Objective: Co-market service for design and creation of targeted gene sequencing panels Dynamic: Genomenon to use its automated machine learning approach and Mastermind Genomic Search Engine to identify biomarker targets associated with diseases and create list of candidate biomarkers which will then be curated based on scientific evidence from the literature Swift to build and validate Accel-Amplicon Custom NGS Panels for targets in question
Zymo Research	CosmosID	<ul style="list-style-type: none"> Objective: Combine firms' respective technologies to create single microbiome analysis product Dynamic: New product will fuse Zymo's tools for sample collection/preservation, nucleic acid isolation and library preparation with CosmosID's curated microbiome database
Thermo Fisher Scientific	Evosep	<ul style="list-style-type: none"> Objective: Develop clinical proteomics workflows Dynamic: Combine Thermo Fisher's mass spec systems with Evosep's liquid chromatography
Atomo Diagnostics	Owen Mumford	<ul style="list-style-type: none"> Objective: Commercialize Atomo's HIV tests in Europe Dynamic: Owen Mumford acquires exclusive rights to Atomo's CE-marked HIV tests and will market them in Europe under Simplitude brand Agreement may be extended to include Atomo's HIV self-test
Centogene	University of Greifswald + University of Rostock	<ul style="list-style-type: none"> Objective: Develop diagnostic tools for personalized, immune-based colon and pancreatic tumor treatments Dynamic: Centogene to genetically profile cancer patients to identify immune-relevant mutations and specific biomarkers for early differential diagnosis and therapy monitoring
Centogene	Aldeyra Therapeutics	<ul style="list-style-type: none"> Objective: Identify patients with Sjögren-Larsson Syndrome (SLS) in support of Aldeyra's effort to develop a treatment Dynamic: Aldeyra to get access to Centogene's CentoMD database of clinically annotated phenotype and genotype variants of rare diseases
Centogene	Orphazyme	<ul style="list-style-type: none"> Objective: Support Orphazyme's clinical trials for treatment of neuronopathic Gaucher disease in India Dynamic: Centogene to process and analyze different sample types from trial participants, including plasma, cerebrospinal fluid and dried blood spots
Microbiotica	Genentech	<ul style="list-style-type: none"> Objective: Develop biomarkers, targets and medicines for inflammatory bowel disease (IBD) Dynamic: Use Microbiotica's metagenomics microbiome platform to analyze patient samples from clinical trials of Genentech's investigational IBD drugs to identify microbiome biomarker signatures of drug response, novel IBD drug targets and live bacterial therapeutic products
iBio	Oneway Diagnostica (Brazil)	<ul style="list-style-type: none"> Objective: Develop point-of-care diagnostic tests for Brazil Dynamic: iBio to provide antigen and antibody manufacturing for product prototype development, regulatory approval, commercial launch and ongoing commercialization Oneway to manage Brazil marketing, distribution and sales Initial focus on Zika and chikungunya
Chembio Diagnostics	Bio-Manguinhos (Brazil)	<ul style="list-style-type: none"> Objective: Commercialize Chembio's point-of-care tests for Dengue, Zika and Chikungunya infection in Brazil Dynamic: Firms have been collaborating since 2016 to develop standalone and multiplex tests for viruses using Chembio's Dual Path Platform (DPP) chromatographic immunoassay technology
Chembio Diagnostics	Massachusetts General Hospital	<ul style="list-style-type: none"> Objective: Develop point-of-care diagnostic tests for patients with fever symptoms Dynamic: Chembio to combine its DPP technology with biomarkers developed at Mass General to develop POC tests for typhoid and febrile illness
OncoDNA	MD Anderson Cancer Center Madrid	<ul style="list-style-type: none"> Objective: Let Center oncologists use OncoDNA genomic analysis tools to diagnose and treat patients Dynamic: OncoDNA also to work with Center to perform genomic studies and cancer research
Laboratory Corporation of America	Mount Sinai Health System	<ul style="list-style-type: none"> Objective: Standardize and improve inpatient lab services across Mount Sinai system Dynamic: LabCorp, which is currently Mount Sinai's primary lab services provider, to standardize test menus, equipment, supplies, logistics and processes at 7 system hospitals
Lucence Diagnostics	NovogeneAIT Genomics Singapore	<ul style="list-style-type: none"> Objective: Develop NGS-based precision cancer treatment tests for Asian market Dynamic: Tests will analyze cancer tissue genetics to help personalize patient treatment regimens
NanoString Technologies	Cancer Therapy Evaluation Program (CTEP) of National Cancer Institute	<ul style="list-style-type: none"> Objective: Study clinical validation and utility of new immune-based gene signatures for informing cancer treatment decisions Dynamic: Use NanoString's PanCancer Immuno-Oncology 360 panel in NCI trials to characterize immune activity and develop predictive gene signatures
NeoGenomics	Pharmaceutical Product Development (PPD)	<ul style="list-style-type: none"> Objective: Offer pathology and molecular testing services to pharma and biotechnology clients Dynamic: NeoGenomics to provide lab testing services to support cancer clinical trial activities performed by PPD Laboratories Firms to also offer PPD clients companion diagnostic development services based on PPD Preclarus data and analytics platform

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	Partner 2	Deal Summary
2bPrecise	PierianDx	<ul style="list-style-type: none"> Objective: Develop tool for point of care precision medicine decision making Dynamic: Combine knowledge base from PierianDx Clinical Genomics WorkSpace platform with clinical information on cancer patients
Qiagen	Freenome	<ul style="list-style-type: none"> Objective: Develop NGS-based companion diagnostics for immuno-oncology Dynamic: Combine Freenome's artificial intelligence genomics platform with Qiagen molecular analysis platforms and co-market technologies to pharmaceutical companies
Qiagen	HTG Molecular Diagnostics	<ul style="list-style-type: none"> Termination of initiative to commercialize NGS-based assay Initiative was the first of multi-project assay development agreement between the firms which remains intact
Adaptive Biotechnologies	Sanofi	<ul style="list-style-type: none"> Objective: Assess minimal residual disease in multiple myeloma patients treated with Sanofi's investigational anti-CD38 monoclonal antibody therapy Dynamic: Use Adaptive's immune repertoire sequencing assay ClonoSeq to do assessment Adaptive to seek regulatory clearance of ClonoSeq for multiple myeloma and receive upfront and potential future milestone payments
Genomind	Albertsons Companies	<ul style="list-style-type: none"> Objective: Provide free education about Genomind's Genecept Assay for pharmacologically treating mental health issues to pharmacy patients at select Albertsons, Jewel-Osco and Acme supermarkets Dynamic: Specially trained pharmacists at select locations may decide to counsel a patient who's had unsuccessful experiences with a prescription drug for depression, anxiety, obsessive-compulsive disorder or other mental illnesses Patient may also agree to have pharmacist contact treating clinician and suggest the Genecept Assay
LexaGene	Stanford University School of Medicine	<ul style="list-style-type: none"> Objective: Leverage Stanford cancer sequencing technology to improve LexaGene's microfluidic instrument Dynamic: LexaGene technology involves single-use disposable microfluidic cartridges to concentrate and purify genetic samples, plus an instrument that does molecular analysis on the samples
Lunaphore Technologies	Vitro	<ul style="list-style-type: none"> Objective: Develop in situ hybridization protocols for RNA and DNA targets in tissue Dynamic: Use Vitro reagents on Lunaphore's prototype microfluidics-based rapid autostaining platform
Rainbow Genomics	Color	<ul style="list-style-type: none"> Objective: Offer hereditary cancer and heart health genetic risk assessment tests in Hong Kong Dynamic: Rainbow to provide its genetic tests for hereditary cancers and heart health conditions Color's CLIA-certified and CAP-accredited California lab to analyze patient samples using NGS
Pro-Lab Diagnostics	Medicortex Finland	<ul style="list-style-type: none"> Objective: Commercialize Medicortex's brain injury detection kit in Canada and UK Dynamic: Pro-Lab to seek regulatory approval and clinical validation of kit Medicortex gives Pro-Lab exclusive rights to sell kit in Canada and UK in return for royalties
Microsoft	Case Western Reserve University	<ul style="list-style-type: none"> Objective: Use quantum computing to improve diagnoses from MRI results Dynamic: Focus of collaboration is magnetic resonance fingerprinting (MRF), an innovative approach to imaging data enabling faster and more accurate detection of developing diseases
Agilent Technologies	University of Duisburg-Essen	<ul style="list-style-type: none"> Objective: Launch new Agilent-sponsored Teaching and Research Center for Separation Dynamic: Center to use Agilent gas and liquid chromatography systems and mass spectrometry instruments to teach students and industry employees about separation science and train them in use of modern analytical equipment
Biosynth	Ramot, the Tel Aviv University Business Engagement Center	<ul style="list-style-type: none"> Objective: Develop diagnostic kits and solutions for rapid pathogenic bacteria detection for food safety, water treatment, hospital and clinical applications Dynamic: Create new joint venture called Nemis Technologies to develop products using AquaSpark, a technology enabling highly sensitive chemiluminescence
Cytox	Mayo Clinic	<ul style="list-style-type: none"> Objective: Develop Cytox's polygenic risk scoring approach for diagnosis of Alzheimer's and other neurological conditions Dynamic: Cytox to test both its current, commercially available and new technology in the pipeline Mayo Clinic's Alzheimer's Disease Research Center to provide biobank samples
Sphingotec	Nexus Dx	<ul style="list-style-type: none"> Objective: Combine technologies to improve decision-making at the point of care in EDs and ICUs Dynamic: Firms to market Sphingotec's acute biomarkers penKid and bio-ADM on Nexus IB 10 immuno-assay-based POC testing platform
Verge Genomics	University of California, San Diego + VIB (Belgian life sciences research institute)	<ul style="list-style-type: none"> Objective: Launch single-cell sequencing project for Parkinson's disease Dynamic: Combine VIB single-cell RNA sequencing technology, UCSD tissue samples and Verge machine learning platform to sequence genes in brain tissue from people with and without Parkinson's
GeneNews	AIM Laboratories	<ul style="list-style-type: none"> Make each firm's tests available to the other's customers

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	Partner 2	Deal Summary
Genomic Vision	Children's Medical Research Institute (Australia)	<ul style="list-style-type: none"> Objective: Develop assay for research of role of telomere length on cardiovascular disease, cancer and other disorders Dynamic: Use Genomic Vision's DNA combing technology in combination with CMRI's extensive clinical cohorts
DISTRIBUTION, SALES & MARKETING AGREEMENTS		
Property Owner	Distributor	Deal Summary
Emosis	5-Diagnostics	<ul style="list-style-type: none"> Product: Emosis' HIT Confirm blood-based test for confirming diagnosis of heparin-induced thrombocytopenia Territories: 36 countries
MolecularMD	Genoptix	<ul style="list-style-type: none"> Product: MRDx BCR-ABL companion diagnostic test to identify chronic myeloid leukemia patients taking Novartis drug Tasigna who are Philadelphia chromosome positive and thus candidates to stop treatment and start treatment-free remission monitoring Territory: US Genoptix exclusive provider of MRDx testing services and kits in US
Precipio	Euroclone Diagnostica	<ul style="list-style-type: none"> Products: Precipio's Ice Cold-PCR DNA enrichment products for use with liquid biopsies Territory: Europe Exclusive in Italy and non-exclusive in rest of Europe
Agendia	Angsana Molecular & Diagnostics Laboratory	<ul style="list-style-type: none"> Products: Agendia's MammaPrint and Blueprint breast cancer tests Territory: Southeast Asia, including Brunei, Singapore, Malaysia, Vietnam and Myanmar
Sentinel Diagnostics	Ortho Clinical Diagnostics	<ul style="list-style-type: none"> Product: Sentinel's CRP Ultra (MP) wide-range C-reactive protein assay Territories: North America, Europe, Africa and Middle East
PierianDx	ScienceVision	<ul style="list-style-type: none"> Product: PierianDx's Clinical Genomics Workspace platform Territory: Asia-Pacific
LICENSES		
Licensor	Licensee	Deal Summary
Philips	MDxHealth	<ul style="list-style-type: none"> Property: Philips' newly validated phosphodiesterase-4D7 prostate cancer biomarker MDxHealth gets worldwide rights to market product as prognostic test
ERS Genomics	NMI Natural and Medical Sciences Institute at University of Tübingen + NMI TT Pharnaservices	<ul style="list-style-type: none"> Property: ERS Genomics' CRISPR-Cas9 genome editing technology NMI and NMI TT get right to access ERS patents for use in expanding their own custom cell-based research services Non-exclusive
SUPPLY, SERVICE & TESTING AGREEMENTS		
Supplier/Service	Client	Deal Summary
Laboratory Corporation of America + Quest Diagnostics	UnitedHealthcare	<ul style="list-style-type: none"> Starting Jan. 1, 2019, LabCorp will no longer be exclusive national lab provider for UnitedHealthcare Quest to get expanded access to UnitedHealthcare's 48+ million members
Laboratory Corporation of America + Quest Diagnostics	Aetna	<ul style="list-style-type: none"> Starting Jan. 1, 2019, Quest will no longer have exclusive preferred lab provider status with Aetna LabCorp to become a preferred national laboratory for Aetna with expanded access to its 20+ million members
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
OncoDNA	Kura Oncology	<ul style="list-style-type: none"> OncoDNA to provide patient-enrollment services for Kura's ongoing clinical study of head and neck squamous cell carcinoma (HNSCC) drug tipifarnib

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

Here's a rundown of the key diagnostic product launches from mid-May through the third week of June:

NEWLY LAUNCHED PRODUCTS & SERVICES

Company(ies)	Product(s)
New England Biolabs	NEBNext Single Cell/Low Input RNA library prep kit for Illumina sequencing instruments
CoreBiome	BoosterShot, metagenomics and strain sequencing services
Agilent Technologies	Range of new in situ hybridization probes
Biocept	CEE-Sure blood collection tubes for research use only
Molecular Health	Version 3.0 of Molecular Health Guide precision medicine software platform
Qiagen	QIAseq 16S/ITS NGS Panels for profiling bacterial and fungal communities using Illumina platforms
Qiagen	UCP Multiplex PCR Kit and kits for profiling microbial communities from complex microbiome samples
Curetis	US commercial launch of Unyvero System molecular diagnostic and Unyvero LRT Application Cartridge for detecting lower respiratory tract infections
Pacific Biosciences	Microbial multiplexing kit for its Sequel single-molecule sequencing instrument
Pacific Biosciences + Phase Genomics	FALCON-Phase genome assembly software combining PacBio single-molecule sequencing data with Hi-C scaffolding technology
Databricks	Databricks Unified Analytics Platform for Genomics
Synthego	Engineered Cells product portfolio giving customers immediate access to Knockout Clone and Pool, and Advanced Cells
Fluidigm	Advanta Sample ID Genotyping Panel for identification and quality assessment of human samples and cell lines in disease research
Laboratory Corporation of America + OmniSeq	OmniSeq Advance, NGS-based molecular cancer assay assessing specific genomic alterations, tumor mutational burden, microsatellite instability, tumor microenvironment and immunotherapy markers
Shimadzu	LCMS-9030 system, a research-grade mass spectrometer
Thermo Fisher Scientific	Thermo Scientific Q Exactive UHMR Quadrupole Mass Spectrometer
Thermo Fisher Scientific	Thermo Scientific Orbitrap ID-X Tribrid Mass Spectrometer
Thermo Fisher Scientific	ChromaCare line of flush solutions and ultra-high performance LC-MS solvents
MediSapiens	Genius, a genomics data management and querying platform
PerkinElmer	Addition of NEXTflex unique dual index barcodes to its NEXTflex library prep products
Castle Biosciences	DecisionDx-CMSeq NGS test for identifying somatic mutations in BRAF and NRAS genes
Laboratory for Advanced Medicine	IvyGene test for detecting DNA methylation patterns consistent with presence of cancer
Asuragen	AmplideX PCR/CE DMPK Kit, research-use-only assay to simplify analysis of repeat expansions in DMPK gene
SomaGenics	RealSeq-biofluids, NGS library construction kit for detecting small RNAs in cell-free biofluids

Top of the News: ANDE Rapid DNA Platform First to Win FBI Approval

“Great news! The FBI just called.”

—Extremely rare phrase almost never uttered except sarcastically

One of the very few exceptions to the above principle is ANDE (previously known as NetBio), a Boston area DNA detection technology developer that just became the first firm to secure official FBI approval for a rapid DNA identification platform.

The Rapid DNA Act

The approval is the first under a 2017 federal law called the Rapid DNA Act which authorizes law enforcement to use rapid DNA analysis technology and upload the results into a federal database to identify perpetrators and exonerate the innocent. But the DNA analysis technology must first be approved before it can be used.

The ANDE System

The ANDE 6C system, which is based on MIT technology, is a two-hour test run on a cheek swab sample using the firm's FlexPlex chemistry, a consumable chip and a ruggedized instrument. Now that it has been FBI-approved, accredited labs will be able to use the ANDE system to process DNA samples and search the results against the program without manual interpretation or technical review. According to a company spokesperson, ANDE is also expected to be the only system eligible for use in police booking stations. The “rapid” part of the system is crucial because it allows for the completion of testing while suspects are still in custody—often for different, unrelated crimes.



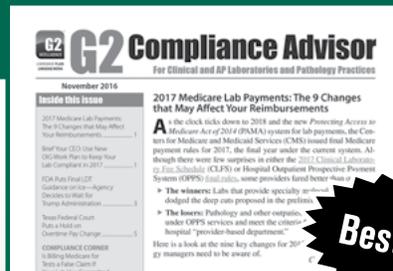
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