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LABORATORY INDUSTRY REPORT™

A DIVISION OF PLAIN LANGUAGE MEDIA

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HIGHLIGHTS

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Upcoming Events

Conference:

Lab Institute 2017
October 25-27
Hyatt Regency Washington on Capitol Hill, Washington, DC
www.labinstitute.com

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

Deal volume in May and June was noticeably higher, especially in terms of M&A activity. There was more global activity over the current than at any other point in 2017, particularly in Asia. Here is a rundown of the big stories and trends in Dx.

M&A

As usual, M&A activity in the diagnostics segment was dominated by the corporate giants. The biggest deal of the period was Thermo Fisher's $7.2 billion acquisition of contract development and manufacturing organization (CDMO) Patheon, a North Carolina-based company that provides drug development support for pharmaceutical firms. Thermo says the deal, which is expected to close by the end of 2017, will secure its access to the $40 billion CDMO market and create $120 million in synergies ($90 million in cost and $30 million in revenues synergies), prompting the company to increase its 2018 adjusted earnings per share by $0.30.

Continued on page 7

FDA Watch: User Fees Dodge a Bullet, a Cancer Drug Approval Breaks New Ground and the Supreme Court Serves Up a Biosims Blockbuster

The FDA budget pot continues to boil. In March, the Trump administration proposed a controversial provision to double the medical user fees that diagnostics, medical device and pharma companies pay to have the FDA review their products. "Industries that directly benefit from FDA's medical product premarket approval ... can and should pay more to support FDA's continued capacity," the administration argued.

But the so-called "recalibration" plan didn't get far. First and foremost, it completely ignored the fact that user fees were the subject of previous negotiations between the FDA and indus-

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FDA Watch, *from page 1*

try. And The FDA Reauthorization Act includes the negotiated rather than the recalibrated fees. And that's one of the reasons the bill enjoys bipartisan support and is expected to pass easily in July.

Undeterred, the White House has reintroduced recalibration as part of its May 23 proposed budget for 2018. In addition to being highly problematic in its timing, the new plan is even more extreme than its predecessor. Instead of doubling, the administration would *triple* user fees to $439 billion. Needless to say, industry has criticized the plan and called on Congress to stick with the negotiated fees which, according to AdvaMed "is beneficial to patients, FDA and American innovation." But while recalibration is likely to pass, it something that industry will have to continue monitoring in the months ahead.

A Landmark Cancer Drug Approval

On May 23, the FDA did something it had never done before by approving a cancer drug administered on the basis of the genomic features of a tumor rather than where in the patient's body the tumor started. The drug, Merck's Keytruda (pembrolizumab) PD-1/PD-L1 inhibitor, was approved for treating adult and pediatric patients with nonoperable or metastatic solid tumors identified as having microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) genetic alterations, a type of tumor most frequently found in colorectal, endometrial and gastrointestinal cancers affecting roughly four percent of advanced cancer cases in the U.S.

Richard Pazdur, acting director of the Office of Hematology and Oncology Products within the FDA's drug division, called the approval "an important first for the cancer community," a sentiment echoed by the medical community. "This is the first time in the history of oncology that a cancer medicine has been approved by the FDA using a pan-tumor predictive biomarker rather than a tumor-specific approach," said Luis A. Diaz, Jr., M.D., from Memorial Sloan Kettering Cancer Center. "This is a transformational milestone in our progress toward personalized immunotherapy," added Diaz.

Biosims Supreme Court Stunner

On June 12, makers of biosimilars, i.e., biologic medical products that are nearly identical copies of original products manufactured by a different company, scored a major legal victory in the U.S. Supreme Court issued a ruling making it easier for them to launch products.

Explanation: Drug makers must give the FDA marketing notice of new products and cannot launch until the FDA issues an approval, a process that takes six months. Amgen argued that biosims makers were subject to the six-month waiting period; Sandoz claimed that imposing such a waiting period would undermine a federal law called the Biologics Price Competition and Innovation Act (BPCIA) designed to encourage biosims production by providing a relatively short product licensing process. The Supreme Court agreed with Sandoz. *Bottom line:* Biosims must file an FDA marketing notice but can launch right away without waiting six months for FDA approval.

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Here's a look at key FDA diagnostics approvals in May and early June:

NEW FDA APPROVALS

Manufacturer(s)	Product(s)
Qiagen	Premarket approval of Artus CMV QS-RGQ molecular diagnostic kit for use on QiaSymphony platform to manage solid organ transplant patients undergoing anti-cytomegalovirus
Becton Dickinson	Extended approval of BD MAX real-time PCR enteric bacterial panel to include molecular test that detects infectious diarrhea caused by intestinal bacteria
Quidel	Approval and CLIA waiver for Sofia Influenza A+B fluorescent immunoassay operating on the Sofia 2 analyzer
Quidel	Approval of molecular assay for detecting *C.diff* infections from stool samples performed on Quidel's Solana platform
Grifols	Investigational New Drug approval of Procleix Babesia assay for blood screening at certain U.S. blood banks
Luminex	Approval of Aries Bordetella Assay to detect respiratory tract infections attributable to *B. pertussis* and *B. parapertussis* from nasopharyngeal swab specimens
GenePOC	Approval Revogene molecular diagnostics instrument
GenePOC	Approval of GenePOC GBS LB molecular assay for detecting Group B streptococcus
BioMérieux	Approval of FilmArray Respiratory Panel 2 (RP2) tests for viruses and bacteria responsible for respiratory tract infections
Roche	Approval of VENTANA PD-L1 (SP263) Assay as complementary diagnostic for PD-L1 status of patients with locally advanced or metastatic urothelial carcinoma for purposes of deciding on treatment with AstraZeneca's anti-PD-L1 immunotherapy IMFINZI
Roche	Approval of cobas e 801 high-volume testing immunoassay module for use on the cobas 8000 modular analyzer series
Novartis	Approval to use Rydapt, acute myeloid leukemia drug, in combination with chemotherapy and testing with Invivoscribe Technologies' LeukoStrat CDx FLT3 Mutation Assay to identify patients who can use drug

New CE Marks

Here's a summary of notable European CE certifications:

NEW CE CERTIFICATIONS

Manufacturer(s)	Product(s)
Singulex	Approval of Sgx Clarity cTnl assay for quantitative measurement of troponin
EntroGen	Approval of BRCA Complete kit for exome sequencing of BRCA1 and BRCA2 genes for use on Illumina's MiniSeq, MiSeq and NextSeq platforms
Multiplicom	Extended approval of BRCA Mastr Plus Dx next-generation sequencing library preparation kit, analysis software and quality control to identify mutations in coding regions of BRCA1 and BRCA2 genes
Great Basin	Approval of molecular diagnostic assay to detect Bordetella pertussis, the bacterium that causes whooping cough
Agilent Technologies	Approval of Dako PD-L1 IHC 28-8 pharmDx test to identify patients with squamous cell carcinoma of the head and neck likely to benefit from using cancer drug Opdivo (Bristol-Myers Squibb); previously, test was approved only as a companion diagnostic for Opdivo

INSIDE THE LAB INDUSTRY

Palmetto Gives Okay to Medicare Coverage of 5 New Molecular Tests

Medicare contractors are slowly coming around on covering unproven molecular assays. The most notable new baby steps come from, Palmetto GBA (Columbia, SC), one of Medicare's most important contractors in the form of draft local coverage determinations (LCDs) providing limited coverage for five new tests.

1. Guardant360 for Advanced Lung Cancer

Test: Guardant360, Guardant Health's liquid biopsy assay for lung cancer.

Proposed Coverage: Guardant360, which came onto the market in 2014 and is now widely ordered, would be covered only for patients with advanced non-small cell lung cancer, i.e., stage IIIB or higher. Conditions vary depending on treatment stage:

Offenses Justifying Imposition of CMPS—Before & After

Diagnosis Stage	Progression Stage
Condition 1: Patient not genomically tested for: ■ EGFR alterations ■ ALK and ROSI rearrangements, or ■ PD-L1expression **Condition 2:** Patient must be ineligible for tissue-based testing because either: ■ Biopsy tissue is insufficient or ■ Biopsy not possible for medical reasons	**Condition 1:** Patient not genomically tested for targets in question **Condition 2:** Tissue-based testing is medically infeasible Coverage also provided for patients progressing on an EGFR tyrosine kinase inhibitor regardless of genetic testing history

The LCD would not cover Guardant360 for:

- Repeat testing for therapeutic monitoring; or
- Assessing germline variants.

Context: The new Guardant360 LCD comes less than three months after Palmetto's approval of molecular blood test Xpresys XL2 for limited lung cancer screening:

- To assess lung nodules of between 8 and 30 mm in diameter; and
- For patients over age 40 who have a pre-test cancer risk of 50 percent or less.

(See *NIR*, June 30, 2016 for Palmetto's coverage criteria for assessing analytical performance of liquid biopsy tests to detect genetic variants in tumors.)

2. Oncotype DX Genomic Prostate Score for Prostate Cancer Risk

Test: Genomic Health, Inc.'s Oncotype DX Genomic Prostate Score (GPS) for assessing the current state and future risk of prostate cancer.

INSIDE THE LAB INDUSTRY

Proposed Coverage: GPS, which is currently covered for clinically-low risk men, would also be covered for patients with favorable intermediate-risk prostate cancer under National Comprehensive Cancer Network (NCCN) guidelines. This would expand the number of Medicare beneficiaries from 50,000 to 80,000.

Context: In January 2017, Palmetto approved the competing drug, Myriad's Prolaris, which measures the aggressiveness of prostate cancer by analyzing 31 cell cycle progression genes, for men with favorable intermediate risk of prostate cancer under NCCN criteria. (See, *LIR* Jan. 6, 2017).

2 New Molecular Tests that Didn't Make the Cut

Not all of the recent Medicare coverage news from Palmetto has been good. Just ask the firms that make the tests that Palmetto refused to cover:

1. Respiratory Virus PCR Tests
On practically the same day it accepted coverage of nucleic acid amplification tests for GI bacteria, Palmetto turned thumbs down on Polymerase Chain Reaction (PCR) testing for respiratory synctial viruses. Pathogen targets in RSV panels don't represent a common syndrome, Palmetto reasons. The multiplex PCR respiratory viral patterns don't meet Medicare "reasonable and necessary" standards, according to the LCD, because they "are effectively a one-size-fits-all diagnostic approach."

2. Prometheus IBD sgi Diagnostic
Prometheus also nixed Prometheus IBD sgi Diagnostic test, which uses panels of serological, genetic immune response and inflammatory biomarkers for differentiating inflammatory bowel disease from Crohn's disease and ulcerative colitis. The draft negative coverage decision cites flaws in the supporting study, including lack of methodology details and replication of the findings.

3. EndoPredict Test to Help Breast Cancer Patients Avoid Chemotherapy

Test: Myriad Genetics's EndoPredict test, which uses a 12-gene molecular assessment score combined with tumor size, nodal status and other features to determine if it's medically safe for clinically low-risk breast cancer patients to skip chemo.

Proposed Coverage: EndoPredict would be covered only for postmenopausal women diagnosed with early-stage estrogen-receptor (ER) positive, HER2-negative breast cancer who either:

- Are lymph node-negative; or
- Have up to three positive nodes and are being considered for adjuvant endocrine therapy.

Context: Two other breast cancer prediction molecular assays on the market have received favorable Medicare coverage determinations from contractor Noridian:

- Oncotype DX Breast from Genomic Health, Inc.; and
- Prosigna from Nanostring Technologies.

4. AlloSure for Kidney Transplant Rejection Risks

Test: CareDx's AlloSure targeted NGS test for quantifying donor-derived cell-free DNA in kidney transplant recipients.

Proposed Coverage: LCD would cover use of AlloSure only for measuring the probability of allograft rejection in kidney transplant recipients for whom there is a clinical suspicion of rejection at least two weeks post-transplant. Other limitations:

- Patients must be over 18; and
- Before ordering, physicians must assess patients for probability of active renal allograft rejection.

Context: CareDx claims that AlloSure is the only non-invasive test that uses donor derived cell-free DNA as a biomarker to identify probability of active rejection and directly measure allograft injury.

5. Nucleic Acid GI Pathogen Tests

Test: Another draft LCD proposes coverage of molecular tests that use nucleic acid amplification to detect gastrointestinal pathogens.

Proposed Coverage: Coverage is limited to tests identifying up to five bacterial targets that Palmetto claims account for 90-95 percent of all foodborne infections: i. *Salmonella*; ii. *Shiga toxin-producing E. coli*; iii. *Shigella*; iv. *Cryptosporidium*; and v. *Campylobacter*. Coverage would not include:

- Testing for viruses due to the lack of virus-specific therapies that viral test results would inform;
- Epidemiologic testing by national, state or local agencies; or
- Testing to confirm another test result.

In addition, GIP test panels cannot be unbundled and billed as individual components. *Exception:* Where *c difficile* is not included in a panel, testing for it "may be reasonable and necessary when ordered additionally," as long as documentation in the medical record supports reasonableness and necessary.

Context: As Palmetto notes, at least five different companies produce FDA-approved GI pathogen assays that meet or exceed the LCD's five-target limit:

GI Pathogen Assays Covered by New Palmetto LCD

Company	Progression Stage
BD Diagnostics	BD MAX Enteric Bacterial Panel
Biofire Diagnostics	FilmArray GI Panel
Hologic	ProGastro SSCS
Luminex	xTAG Gastroenterology Panel
Nanosphere	Verigene Enteric Pathogens

Takeaway: Although these are positive developments for the molecular diagnostics community, the pace of Medicare coverage remains piecemeal and frustratingly slow. Although influential, Palmetto is only one of several key Medicare contractors. Moreover, the spate of favorable LCDs belies the fact that a number of other commercially popular molecular tests failed to make the cut. *(See the related item on page 5.)*

Diagnostic Deals, *from page 1*

Thermo also made news by disclosing the terms of its previous acquisitions. According to a May 10, SEC filing, the firm paid $94 million (net of cash acquired in the deal) to acquire Core Informatics in March. The informatics firm has since been made part of Thermo's Analytical Instruments segment. The other key bit of M&A intelligence disclosed in the SEC filing is the total purchase price of Thermos's February acquisition bioproduction software maker Finesse Solutions, i.e., $220 million in cash (net of cash acquired).

Quest led all companies in deal volume with three acquisitions, including a June 12 agreement to purchase two lab businesses in Lewisville, Texas, Med Fusion and Clear Point, from some of the state's biggest network providers, including non-profit Baylor Scott & White Health and The US Oncology Network, whose The Network is the largest oncology network in the country with more than 400 locations and 1,400 community-based doctors. Under the deal, Quest will become a preferred provider of oncology diagnostics for The Network.

Quest's other move was officially closing its February purchase of PeaceHealth Laboratories' outreach service operations in Oregon, Washington and Alaska. PeaceHealth will retain ownership of 11 of the labs but Quest will take over their management.

Speaking of consummating earlier deals, LCA closed its acquisition of PAML (Pathology Association Medical Laboratories, LLC) from joint owners Providence Health and Catholic Health Initiatives. In addition to the outreach lab operations, LCA acquires PAML's interests in five lab-related joint ventures.

Rosetta Genomics also made news in May by announcing plans to sell PersonalizeDx, the fluorescence in situ hybridization-based cancer tests seller (and CLIA lab business operator) it acquired just two years ago. Rosetta's strategy is to concentrate on U.S. commercialization of its RosettaGx Reveal assay business.

Eurofins Scientific was the most active M&A player in Europe, acquiring a pair of German firms including DNA sequencing and genetic testing firm GATC Biotech and Hygel (*Laboratoriumsmedizin am Hygiene-Institut*), a €35 million lab group operating out of seven sites in Germany.

Strategic Alliances

There were a slew of strategic partnerships, including a pair of cancer-related deals from Royal Phillips: a collaboration with Intermountain genomics spinout Navican to offer oncology services to health systems, and a partnership with Memorial Sloan Kettering designed to leverage Phillips's IntelliSpace platform to develop pancreatic cancer diagnostics.

The traffic in lab-pharma alliance making was slower than usual but there were a couple of notable deals, including:

- Qiagen's collaboration with Bristol-Myers Squibb to develop NGS assays for cancer treatment predictions that can be used for BMS's immune-oncology therapies; and

- Guardant Health's agreement to provide its Guardant360 liquid cancer biopsy to Pfizer for use in clinical trials; and
- The partnership of Thermo Fisher and Agios Pharmaceuticals to develop and commercialize NGS diagnostics for the latter's investigational cancer drug ivosidenib.

Other notable deals included new product development arrangements in the genomics space pairing:

- Biocartis and MRC Technology for molecular tests to be used on Biocartis's Idylla platform;
- Agilent Technologies and Agendia for NGS molecular breast cancer test kits;
- Illumina and Integrated DNA Technologies for NGS target enrichment products; and
- OncoDNA and Cryogene for personalized cancer treatments.

Here's a graphic rundown of key diagnostic deals in May and early June:

MERGERS & ACQUISITIONS		
Acquiring Company	**Target(s)**	**Deal Summary**
Quest Diagnostics	Med Fusion and Clear Point (owned by Baylor Scott & White Health,; The US Oncology Network); Texas Oncology; and Pathologists Bio-Medical Laboratories)	▪ Price: Undisclosed ▪ Status: Expected to close in Q3 ▪ Quest to become advanced oncology diagnostics preferred provider for The US Oncology Network, the largest not-for-profit health care system in Texas
Quest Diagnostics	PeaceHealth, non-profit health system in Alaska, Washington, Oregon	▪ Price: Undisclosed ▪ Status: Closed in May ▪ Quest acquires PeaceHealth Laboratories' outreach laboratory services operations ▪ PeaceHealth keeps 11 labs which Quest will professionally manage
Transgenomic	Precipio Diagnostics	▪ Price: New firm, to be called Precipio Inc., to receive up to $7 million in funding from upcoming private placement ▪ Status: Shareholders of both companies approve proposed merger announced in October 2016
Eurofins Scientific	GATC Biotech	▪ Price: Undisclosed ▪ Status: Expected to close in July ▪ Eurofins expands genetic testing and DNA sequencing capabilities ▪ GATC roughly €20 million ($22.5 million) annual revenues
Sysmex	Oxford Gene Technology	▪ Price: Undisclosed ▪ Status: Expected to close in mid-June ▪ OGT corporate structure to be kept intact but will become wholly-owned subsidiary of Sysmex
Grail	Cirina	▪ Merger of 2 startups ▪ Objective: Commercialization of liquid biopsy tests for early cancer detection ▪ Cirina to operate as subsidiary of Grail
Stago Group	HemoSonics LLC	▪ Price: Undisclosed ▪ Status: Closed in May ▪ Stago enhances point-of-care testing capabilities via acquisition of HemoSonics' SEER technology (Sonic Estimation of Elasticity via Resonance) and associated Quantra Hemostasis Analyzer
Quidel	InflammaDry and AdenoPlus businesses owned by RPS Diagnostics	▪ Price: $14 million in cash ▪ Status: Closed in May ▪ Target companies sell rapid, lateral flow assays to detect infectious and inflammatory eye conditions that generate roughly $5 million in annual revenue ▪ Quidel will manufacture products in its San Diego facility

MERGERS & ACQUISITIONS		
Acquiring Company	**Target(s)**	**Deal Summary**
Laboratory Corporation of America Holdings	Pathology Associates Medical Laboratories, LLC—jointly owned by Providence Health & Services and Catholic Health Initiatives	▪ Price: Undisclosed ▪ Status: Closed in May ▪ LabCorp also acquires PAML's interest in 5 joint ventures ▪ Providence, CHI and hospital joint venture owners will continue providing in-patient hospital lab services ▪ LabCorp will provide outreach testing services and reference lab services currently provided by PAML and joint ventures
Thermo Fisher Scientific	Patheon	▪ Price: $7.2 billion--$35 per share in cash + assumption of $2 billion debt ▪ Status: Expected to close by end of 2017 ▪ TF gets access to $40 billion contract development and manufacturing organization market
Thermo Fisher Scientific	Core Informatics	▪ Price: $94 million (net of acquired cash) ▪ Status: Closed March ▪ Informatics firm had $10 million in 2016 revenues ▪ TF makes firm part of its Analytical Instruments segment
Thermo Fisher Scientific	Finesse Solutions	▪ Price: $220 million (net of acquired cash) ▪ Status: Closed February ▪ Bioproduction automation systems and software firm had roughly $50 million in 2016 revenues
Lonza	HansaBioMed Life Sciences (Estonia)	▪ Price: $94 million (net of acquired cash) ▪ Status: Closed May ▪ Acquisition gives Lonza access to exosomes-based cancer assays market ▪ As part of strategy, Lonza also cuts separate deal for an equity stake in Italian molecular diagnostics startup Exosomics
UK's Medical Research Council Consortium for Mass Cytometry	Fluidigm	▪ Price: Undisclosed ▪ Status: Closed ▪ Asset sale in which MRC acquires 7 of Fluidigm's Helios mass cytometry systems
Eurofins Scientific	MVZ für Laboratoriumsmedizin am Hygiene-Institut (Hygel)	▪ Price: Undisclosed ▪ Status: Expected to close in July ▪ Hygel is a group of diagnostics labs operating out of 3 sites and 4 hospitals in Germany with over €35 million ($38.3 million) in 2016 revenues

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	**Partner 2**	**Deal Summary**
Biocartis	MRC Technology	▪ Objective: Develop molecular Dx tests for use on Biocartis's Idylla platform ▪ Dynamic: MRCT to act as a development contractor and Biocartis to commercialize tests under its own label ▪ First project: Develop liquid biopsy test to monitor metastatic breast cancer patients for resistance to hormone therapy
Qiagen	Bristol-Myers Squibb	▪ Objective: Develop NGS (next-generation sequencing) assays for cancer treatment ▪ Dynamic: Sides to work together to create gene expression panels to be used as predictive tools for BMS immuno-oncology therapies
Qiagen	Maccura Biotechnology	▪ Objective: Commercialize Q's GeneReader NGS system in China and develop gene panels for China market ▪ Dynamic: Form joint venture called Maqgen based in Chengdu ▪ Maccura to own 60% and Qiagen 40% (which could go as high as 49% in 3 years) ▪ Qiagen to continue operating its wholly-owned subsidiary in China
Jackson Laboratory	3 groups in China: i. Wenzhou Municipal People's Government; ii. Ouhai District People's Government; iii. Wenzhou Medical University (WMU)	▪ Objective: Research genomic propensities for disease ▪ Dynamic: Chinese partners to form Wenzhou Institute for Genomic Medicine to do research under Jackson's management ▪ Jackson scientists to form genomics research collaborations with WMU investigators in US and China
Guardant Health	Pfizer	▪ Objective: Cancer research ▪ Dynamic: Guardant to provide Pfizer its Guardant360 liquid biopsy cancer assay to for use in clinical trials

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	**Partner 2**	**Deal Summary**
Agilent Technologies	Agendia	▪ Objective: Develop NGS molecular breast cancer diagnostics kit ▪ Dynamic: Use Agilent's SureSelect target enrichment system to develop RNA sequencing kit version of Agendia's microarray-based MammaPrint 70-gene breast cancer recurrence risk test and BluePrint breast cancer subtyping assay
Royal Philips	Navican (Intermountain Healthcare genomics spinout)	▪ Objective: Furnish end-to-end precision oncology services for health systems ▪ Dynamic: Integrate Navican's TheraMap services with the Philips's IntelliSpace Genomics platform
Royal Philips	Memorial Sloan Kettering Cancer Center (NYC)	▪ Objective: Develop precision pancreatic cancer diagnostics ▪ Dynamic: Leverage Phillips's IntelliSpace technology to resolve single cell-level differences between (and within) tumors
Indivumed	Intermed	▪ Objective: Expand personalized cancer testing market share in Germany ▪ Dynamic: Intermed to support growth of Indivumed's cancer database in Germany ▪ Intermed to distribute Indivumed's Dx tests via its partnership with physician-managed lab network LADR Laborverbund
Illumina	Integrated DNA Technologies	▪ Objective: Create NGS target enrichment products ▪ Dynamic: Companies to develop portfolio of indexed adapters that IDT will manufacture ▪ Deal includes co-marketing agreement pairing couples Illumina's TruSeq and Nextera library prep kits with IDT's xGen Exome Research Panel
Rosetta Genomics	Meir Medical Center (in Israel)	▪ Objective: Develop a microRNA-based test to identify non-small cell lung cancer (NSCLC) patients who would benefit from a specific class of immunotherapeutics ▪ Dynamic: Launch study to identify miRNAs differentially expressed between PD-L1-positive and PD-L1-negative NSCLC samples
Thermo Fisher Scientific	Agios Pharmaceuticals	▪ Objective: Develop and commercialize NGS companion diagnostic for Agios' investigational cancer drug ivosidenib
One BioMed	A*Star's Genome Institute of Singapore	▪ Objective: Develop molecular diagnostic infectious disease tests for Asian market ▪ Dynamic: Tests to be created out of newly established joint testing lab
OncoDNA	Cryogene (OncoDNA's current distributor for Middle East)	▪ Objective: Development of personalized cancer treatments ▪ Dynamic: Launch study of effectiveness of OncoDNA's liquid biopsy technology to assess clinical utility of personalized treatments for metastatic cancer
Alexion Pharmaceuticals	Rady Children's Institute	▪ Objective: Develop precision medicine platform for use in newborns with rare genetic disorders ▪ Dynamic: Platform to be based on Alexion's SmartPanel
GeneNews	Any Lab Test Now	▪ US partnership with lab testing services provider covering GeneNews' portfolio of early cancer detection tests
Biocept	Addario Lung Cancer Medical Institute	▪ Objective: Detect and assess lung cancer treatment biomarkers ▪ Partners to evaluate use of Biocept's Target Selector liquid biopsy platform in lung cancer clinical study
Admera Health	University of Rochester School of Medicine and Dentistry	▪ Objective: Evaluate use of Admera's 50-gene PGxOne Plus pharmacogenomics test in guiding pain management decisions after acute dental surgery ▪ Dynamic: Test to be used on patients in clinical study
MDxHealth	Maastricht University	▪ Objective: Development genetic and epigenetic cancer diagnostics ▪ Dynamic: Expansion of existing partnership to, among other things, cover recently launched SelectMDx prostate cancer test
Critical Path Institute	Translational Genomics Research Institute	▪ Objective: Develop personalized treatments for tuberculosis ▪ Dynamic: Collaboration to sequence thousands of bacteria isolated by tuberculosis
Tempus	Basser Center for BRCA at University of Pennsylvania's Abramson Cancer Center	▪ Objective: Develop and improve personalized treatments for heritable BRCA mutations ▪ Dynamic: Tempus to work with Basser investigators to analyze existing molecular and clinical data of patients treated at Center ▪ Tempus has similar collaborations with University of Chicago, Duke, University of Michigan, Ohio's University Hospitals Seidman Cancer Center and Mayo Clinic
Fulgent Genetics	Xilong Scientific and Fuzhou Jinqiang Investment Partnership	▪ Objective: Offer genetic testing in China ▪ Dynamic: Form joint venture called Fujian Fujun Gene Biotech ▪ Fulgent to supply $8.7 million in genetic sequencing and other equipment and own 30% ▪ Xilong will own 51% and FJIP 19% ▪ Joint ownership term of 20 years

DISTRIBUTION, SALES & MARKETING AGREEMENTS		
Property Owner	**Distributor**	**Deal Summary**
LifeCodexx	LifeCell	▪ Product: LifeCodexx's PrenaTest noninvasive prenatal screening test ▪ Territory: India ▪ LifeCell to sell test under its BabyShield brand
Pathway Genomics	Salud Interactiva	▪ Products: Pathway's NGS assays ▪ Territory: Mexico
Thermo Fisher Scientific	Biognosys	▪ Co-marketing deal ▪ Products: TF's Orbitrap mass spectrometers and Biognosys' Spectronaut Pulsar software ▪ Two companies also to collaborate in developing data-independent acquisition-related workflows
Streck	Nordic BioSite	▪ Products: Streck's cell stabilization and molecular products ▪ Territories: Sweden, Finland, Denmark and Norway ▪ In April, Streck concluded distribution deals covering China, Switzerland and Austria
Streck	Ngaio Diagnostics	▪ Products: Streck's cell stabilization and molecular products ▪ Territory: New Zealand
Streck	Genomax Technologies	▪ Products: Streck's cell stabilization and molecular products ▪ Territories: Singapore and Malaysia
Mobidiag	Wallac (PerkinElmer subsidiary)	▪ Product: Amplidiag product line ▪ Territories: Israel, Botswana, Ghana, Ivory Coast, Kenya, Mauritius, Morocco, Mozambique, Nigeria, Rwanda, Senegal and Uganda ▪ Expansion of current deal allowing Wallac to distribute Amplidiag in South Africa
OncoDNA	Providens	▪ Products: OncoDNA's cancer genomic tests ▪ Territories: Serbia, Croatia, Bosnia-Herzegovina, Slovenia, Montenegro and Macedonia
Orig3n	Innovasalud	▪ Products: LifeProfile genetic assessment tests including Fitcode, Aura, Fuel, Bliss and Bloom ▪ Territory: Mexico ▪ Co-branding deal
Rosetta Genomics	Cytolog Laboratories	▪ Product: RosettaGX Reveal thyroid test ▪ Territory: Brazil ▪ Exclusive ▪ Rosetta's first distribution deal in South America
Protea Biosciences	Proteos (contract research organization)	▪ Products: Co-marketing deal covering both Protea's bioanalytical services and Proteos' protein production solutions ▪ Territory: Not disclosed

LICENSES		
Licensor	**Licensee**	**Deal Summary**
Atum	Horizon Discovery	▪ Cross-licensing agreement ▪ Property: Atum gets right to combine Horizon's CHO Source platform and glutamine synthetase knockout CHO K1 line with its own Leap-In transposase technology as a cell line development service ▪ Property: Horizon gets exclusive license to a vector suite developed by Atum for the CHO Source platform and right to offer its customers no-fee access to Leap-In system
Johns Hopkins University	Qiagen	▪ Property: Genetic biomarkers used to assess microsatellite instability (MSI) and mismatch repair (MMR) in all sample and cell types ▪ Territory: Worldwide ▪ Qiagen gets right to commercialize NGS assays assessing MSI and MMR status
ERS Genomics	Taconic Biosciences	▪ Property: ERS's CRISPR gene-editing technology (aka "the UC Berkeley patent") ▪ Territory: Worldwide ▪ Non-exclusive ▪ Taconic gets right to use CRISPR to generate unique murine models
ERS Genomics	Oxford Genetics	▪ Property: ERS's CRISPR gene-editing technology (aka "the UC Berkeley patent") ▪ Territory: Undisclosed ▪ Non-exclusive ▪ Oxford gets right to use CRISPR to provide genome-engineering services, in cell line development and gene therapy viral vector improvement, and for development and sale of research tools and reagents
Thermo Fisher Scientific	One Lambda	▪ Property: TF's technology that uses microarrays to measure transcript levels to diagnose rejection of solid organ transplants ▪ Territory: Undisclosed ▪ Exclusive

LICENSES		
Licensor	**Licensee**	**Deal Summary**
Atum (formerly known as DNA2.0)	Thermo Fisher Scientific	▪ Product: Atum's Gene Designer 2.0 software ▪ Territory: Undisclosed
Oxford BioDynamics	Nova Satra Diagnostics Asia	▪ Product: OB's EpiSwitch technology platform ▪ Territories: 13 territories in Asia ▪ Exclusive ▪ NSDA gets right to use EpiSwitch develop and commercialize non-invasive breast cancer testing and is solely responsible for securing any required regulatory approvals
UCLA	GWG Holdings (parent company of life insurance firm GWG Life)	▪ Property: Technology using epigenetic markers to predict life expectancy ▪ Territory: Undisclosed ▪ Exclusive
Boston Children's Hospital	Cambridge Epigenetix	▪ Property: DNA methylation technology for identifying cancer biomarkers ▪ Territory: Undisclosed ▪ Exclusive
Becton Dickinson	Roche	▪ Property: BD's patented stochastic labelling technology which uses molecular barcodes to count individual DNA, RNA and other complex molecules ▪ Territory: Undisclosed ▪ Non-exclusive

SUPPLY, SERVICE & TESTING AGREEMENTS		
Supplier	**Client**	**Deal Summary**
Interpace Diagnostics	Einstein Medical Center of Philadelphia	▪ Deal gives Einstein researchers access to Interpace's ThyGenX oncogene panel and ThyraMir microRNA gene expression classifier, which are used to diagnose thyroid nodules with indeterminate cytology