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LABORATORY INDUSTRY REPORT™

A DIVISION OF PLAIN LANGUAGE MEDIA

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HIGHLIGHTS

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Upcoming Events

Conferences:

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

Lab Reimbursement Summit 2018
December 8, 2017
Holiday Inn Airport (South)
Atlanta, GA
www.lableadershipsummit.com

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

Strategic alliance rather than M&A remains the preferred form of strategic interaction in the lab industry.

M&A

The preference of diagnostic companies to work with rather than digest each other belies the fact that billion-dollar M&A deals are taking place. A trio of them made the headlines this month:

Thermo Fisher-Patheon: On Aug. 29, Thermo Fisher Scientific completed its $7.2 billion purchase of contract development and manufacturing organization (CDMO) Patheon.

LabCorp-Chiltern: On Sept. 1, LabCorp wrapped up its $1.2 billion cash acquisition of contract research organization Chiltern.

Abbott-Alere: Meanwhile, after seeking to bail, Abbott is now doing its best to complete its $5.3 billon Alere acquisition alive,

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FDA Watch: Diagnostics Industry is Losing a Longstanding "Frenemy"

The diagnostics community is saying goodbye to a frenemy of 25 years. On Aug. 29, Alberto Gutierrez, director of the FDA Office of In Vitro Diagnostics (OIVD), announced that he will step down from the agency at the end of September.

Gutierrez the Friend

Gutierrez has been a central figure in moving the FDA forward on precision medicine and next-generation sequencing (NGS) tests. In 2009, he took over the OIVD, which was created to consolidate pre-market and post-market in vitro diagnostics into a single office. Under Gutierrez's leadership, the agency liberalized its approach to precision medicine and began working with the diagnostics industry to streamline procedures and ease approval

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FDA Watch, *from page 1*

of personalized treatments and companion tests identifying patients for those therapies. According to the non-profit Personalized Medicine Coalition, precision treatments accounted for over 20 percent of new molecular entities approved by the FDA in the past three years.

Under Gutierrez's leadership at OIVD, the agency put out draft guidelines on how labs could demonstrate analytical validity for germline NGS tests and encouraged data sharing by proposing the use of public variant databases to establish clinical validity of NGS tests. More recently, the agency approved the first NGS-based companion diagnostic and the first panel CDx that can identify best responders to multiple lung cancer drugs.

His tenure also coincided with the FDA crack down on direct-to-consumer (DTC) marketing of health-related genetic tests by companies like 23andMe. But while the agency thwarted sale of genetic tests for serious diseases like Alzheimer's without a prescription, the Gutierrez-run OIVD took a more accepting approach to DTC access of raw genomic data for recreational genomics, such as ancestry testing.

Gutierrez the Enemy

However, while his legacy will be more positive than negative, Gutierrez's tenure as OIVD director will also be associated with the FDA's controversial policy to regulate LDTs. Historically, the FDA left such regulation to CMS under CLIA. Believing that LDT marketing was getting out of hand, Gutierrez was one of the architects of the 2014 draft regulatory guidance proposing tight FDA control over LDTs.

Gutierrez's departure comes at a time when the agency appears to be backing away from heavy-handed regulation of LDTs. After declining to issue a final version of the draft guidance at the end of 2016, the FDA outlined a softer, more collaborative approach in a January discussion paper. However, while it strikes a tone that is more welcoming to the industry with regard to LDTs regulation, the discussion paper does not go as far as dropping the idea altogether. (See "Discussion Paper Signals New Approach to LDTs Regulation, *LIR*, Jan. 2017). "It's very much unknown how laboratories are going to be regulated, if at all, on LDTs," Gutierrez is recently quoted as saying.

Here's a look at key FDA diagnostics approvals in late August through September:

NEW FDA APPROVALS

Manufacturer(s)	Product(s)
CDC	Approval of: ■ Human Influenza Virus Real-Time RT-PCR Diagnostic Panel; *Influenza A/B Typing Kit; Influenza A Subtyping Kit (ver 2); *Influenza B Lineage Genotyping Kit; and ■ Influenza A/H5 Subtyping Kit (ver 3)
Agilent	Approval of GenetiSure Dx Postnatal Assay
Abbott Labs	Approval of i-STAT Hematocrit test for use on firm's i-STAT Alinity platform

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NEW FDA APPROVALS, *Cont'd.*

Manufacturer(s)	Product(s)
Immco Diagnostics	Approval of ImmuLisa Enhanced Anti-Mitochondria IgG Antibody ELISA to aid in diagnosing primary biliary cirrhosis in conjunction with other lab tests
Viramed Biotech	Approval of Borrelia B31 ViraChip IgM Test Kit for detecting IgM antibodies
Biocartis	Approval of Idylla Respiratory Panel (IFV-RSV)
Ortho Clinical Diagnostics	Approval of Vitros Immunodiagnostic Proeducts Anti-HBe Assay for diagnosing hepatitis B infection in individuals with acute or chronic hepatitis B, or who are recovering from hepatitis B infection
Ortho Clinical Diagnostics	Approval of Vitros Immunodiagnostic Products HbeAg Assay for diagnosing hepatitis B infection in individuals with acute or chronic hepatitis B, or who are recovering from hepatitis B infection
Ortho Clinical Diagnostics	Approval to market itsSera blood-grouping reagents with its ID-Micro Typing System gel card technology for extended phenotype testing

New CE Marks & Global Certifications

Here's a summary of notable European CE certifications:

NEW CE CERTIFICATIONS

Manufacturer(s)	Product(s)
Mologic	Approval of BVPro, point-of-care rapid bacterial vaginosis diagnostic test
Tetracore	Approval of T-Cor 8 portable real-time PCR thermocycler diagnostic system
Shuwen Biotech	Approval of real-time PCR-based EGFR detection kit for lung cancer
Sciex	Approval of Topaz clinical LC-MS/MS system
IntegraGen	Approval of miRpredX 31-3p, test kit for predicting patient response to anti-EGFR therapy
PlexBio	Approval of PlexBio 100, second-generation fluorescence analyzer
iCubate	Approval of iC-System platform for rapid diagnosis of pathogenic bacteria associated with bloodstream infection
iCubate	Approval of iC-GPC assay
Vela Diagnostics	Approval of NGS-based Sentosa SQ HIV genotyping assay

New international approvals included:

- China Food and Drug Administration registration of Isohelix's DNA buccal swabs; and with the; and
- Agência Nacional de Vigilância Sanitária (Brazil) B-GMP approval of Premaitha Health's Iona test.

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

Although it did not launch any new products, Quest announced that its existing low density lipoprotein (LDL) cholesterol tests are using a new calculation that not only improves accuracy but also eliminates the patient's need to fast before being tested. This is the first nonfasting lipid test, the company claims.

September new product launches also featured several tests capable of detecting multiple targets in a single swoop, including:

- The Variantyx Unity genomic test that identifies small sequence changes, structural variants, trinucleotide repeat expansions and mitochondrial variants from a single DNA sample; and
- Bio-Rad's ZDC Multiplex RT-PCR , research-use only assay for simultaneous screening of Zika, dengue and chikungunya arbovirus RNA from a single sample; and
- Explify Respiratory, a next-generation sequencing assay capable of spotting over 200 respiratory infection pathogens in a single test and maiden launch from the collaboration between ARUP Labs and IDbyDNA, Inc.

Here's a rundown of the other key diagnostic product launches from late August through the third week of September.

NEWLY LAUNCHED PRODUCTS & SERVICES

Company(ies)	Product(s)
ARUP Laboratories and IDbyDNA, Inc.	Explify Respiratory, next-generation sequencing test for respiratory infections
Horizon Discovery	Expansion of its functional genomic screening portfolio to include CRISPRi (interference) and CRISPRa (activation) screening
Qnostics	ME Evaluation Panel for meningitis/encephalitis
Phosphorus	Test for genetic conditions associated with vision loss and blindness
Phosphorus	Pharmacogenomic test assessing efficacy of various drugs based on genetic makeup
BC Platforms	BC|RQUEST, a system for analyzing aggregated genomic and clinical data from multiple biobanks
Variantyx	Variantyx Unity, test identifying small sequence changes, structural variants, trinucleotide repeat expansions and mitochondrial variants from single DNA sample
DiaSorin Molecular	Simplexa C. difficile Direct Assay for detecting infection from *C. difficile* toxin B gene in liquid or unformed stool samples
Bio-Rad Laboratories	ZDC Multiplex RT-PCR , research-use only assay for simultaneous screening of Zika, dengue and chikungunya arbovirus RNAs from single sample
Becton Dickinson	BD Rhapsody, platform for single cell RNA analysis
Tecan	Resolvex A200, positive pressure workstation for LC-MS sample prep
Quest Diagnostics	New version of its LDL cholesterol test that improves accuracy and eliminates patient's need to fast before testing
Eurofins Genoma	GeneSafe, non-invasive prenatal test that screens for both de novo and inherited single-gene disorders
Myriad Genetics	riskScore, for measuring a woman's risk of breast cancer via algorithm combining analysis of 80 SNPs and personal and family cancer history

Company(ies)	Product(s)
Ranomics	VariantFind, DNA libraries creation platform
Intermountain Precision Genomics Core Laboratory	RxMatch, new service enabling physicians to implement personalized medicine when prescribing medications
Biocept	Target Selector liqud biopsy assay for mutations in NRAS oncogene
Thermo Fisher	Ion AmpliSeq Immune Repertoire Assay Plus, TCR Beta, research-use-only sequencing panel for immuno-oncology
Thermo Fisher	Ion Torrent Oncomine Lung Cell-Free Total Nucleic Acid Research Assay
Cynvenio Biosystems	PD-L2 expression test, research-use-only test that measures PD-L2 expression in circulating tumor cells from a simple blood draw
Cynvenio Biosystems	ClearID HER2 Expression, liquid biopsy test allowing for real-time monitoring of HER2 levels using a normal blood draw
Sunquest Information Systems	Sunquest Mitogen, laboratory information management system and genetic analysis software platform
Natera	Signatera, research-use-only circulating tumor DNA test

Diagnostic Deals, *from page 1*

extending its previously announced cash tender offer for Alere Series B convertible stock three times. Alere is clearing the antitrust deck by selling off assets, including its Triage BNP assay business and San Diego facilities when the Abbott deal goes through. After announcing sale to Quidel in July, the company unveiled new terms on Sept. 18. Rather than $440 million, Quidel will pay $280 million for BNP, most of it deferred. Quidel will also have "control over the entirety of the BNP business." In the original deal, Abbott retained about $50 million worth of distribution rights.

Strategic Alliances

Product integration was the flavor of the month in strategic alliances. Significant deals included:

- Qiagen's integration of its circulating cell-free DNA blood collection tubes into Clinical Genomic's liquid biopsy colorectal cancer recurrence test;
- A pair of integrations involving FDNA's Face2Gene phenotyping applications—one with Ambry Genetics and the other with Variantyx; and
- The integration of DNAnexus's cloud-based genome informatics platform with Edico Genome's Dragen Genome Pipeline analysis technology.

Here's a graphic summary of the key diagnostic deals from late August through the first three weeks of September:

MERGERS, ACQUISITIONS & ASSET SALES		
Acquiring Company	**Target(s)**	**Deal Summary**
Quidel	Alere's triage MeterPro cardiovascular and toxicology assets and B-type Naturietic Peptide (BNP) assay business	▪ Price: $280 million, including $240 million deferred for BNP + $40 million in contingent payments ▪ Status: Expected to close Oct. 31 ▪ Sale contingent on consummation of Abbott Alere merger which is expected on Sept. 30 ▪ Revised deal terms give Quidel complete control over BNP at lower purchase price
Thermo Fisher Scientific	Patheon	▪ Price: $7.2 billion in cash to acquire 95.3% of Patheon's outstanding shares at $35 per share ▪ Status: Close of deal announced in May ▪ Acquisition of Durham, NC-based pharma and biopharm contract development and manufacturing organization which generated approximately $1.9 billion in 2016 revenue
LabCorp	Chiltern (UK CRO)	▪ Price: $1.2 billion all-cash transaction ▪ Status: Closed ▪ LabCorp to incorporate Chiltern into its drug development business creating CRO unit with over 20,000 employees worldwide
LabCorp	ChromaDex	▪ Price: Undisclosed ▪ Status: Agreement signed with expected Sept. closing date ▪ LabCorp to acquire ChromaDex's analytical health, wellness and nutrition testing services which it will then offer via its Covance Food Solutions business
Pragmin Prognosis	Rosetta Genomics' PersonalizeDx unit	▪ Price: $2.9 million cash, $1.25 million of which to be paid at closing and rest over time ▪ Status: To close late Sept. or early Oct. ▪ Rosetta paid $2 million for PersonalizeDx in 2015 ▪ Divestiture enables Rosetta to cut operating costs and focus on its Reveal test product
Precision for Medicine	Agility Clinical (Carlsbad, CA CRO)	▪ Price: Undisclosed ▪ Status: Closed ▪ Agility Clinical focuses on clinical development of rare diseases and orphan therapies
Metabolon	Metabolomic Discoveries	▪ Price: Undisclosed ▪ Status: Closed ▪ Acquisition of Berlin-based firm gets Metabolon into Europe after entering into Asia and Middle East collaborations earlier in 2017

MERGERS, ACQUISITIONS & ASSET SALES		
Acquiring Company	**Target(s)**	**Deal Summary**
ExcitePCR (subsidiary of PositiveID)	PositiveID	▪ Price: Undisclosed ▪ Status: Acquisition contingent on consummation of $3 million+ finance deal ▪ ExcitePCR to acquire PositiveID's stake in FireFlyDX point-of-care portable diagnostic system for detecting pathogens in 30 minutes

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	**Partner 2**	**Deal Summary**
iBio	TheoremDx	▪ Objective: Develop proteins for use in rapid diagnostic testing of tropical diseases ▪ Dynamic: iBio to develop proteins for TheoremDx to use with its point-of-care testing platform for Zika, Dengue, Chikungunya and West Nile viruses
Genomic Health	Biocartis	▪ Objective: Develop *in vitro* diagnostic version of Genomic Health's Oncotype DX breast cancer assay on Biocartis' Idylla platform ▪ Dynamic: Genomic Health to pay Biocartis $3.3 million for exclusive worldwide rights to develop and commercialize Oncotype DX Breast Recurrence Score test on Idylla—enabling its customers to perform test locally in their own facilities ▪ Genomic Health gets option to expand arrangement to oncology and urology tests
Curetis	MGI (subsidiary of BGI Group)	▪ Objective: Development of NGS tests for microbial infections ▪ Dynamic: Combine Curetis' Unyvero L4 Lysator PCR platform with MGI's SP100 Sample Preparation System and MGISeq NGS sequencers ▪ Curetis to provide sample prep technologies and panel and NGS assay design ▪ MGI to furnish hardware, develop automated workflow and manufacture the NGS assays ▪ MGI responsible for validating and securing regulatory approvals for the assays
PerkinElmer	In-Depth Genomics (IDG)	▪ Objective: Genetic diagnosis of neurological conditions via IDG's Whole Genome Sequencing Diagnostic Program ▪ Dynamic: IDG to offer program free to physicians ▪ PerkinElmer Genetics to provide clinical WGS, data interpretation services, and diagnostic report generation to IDG ▪ IDG to use de-identified genomic and clinical data to support R&D in rare neurological conditions
RPRD Diagnostics	Orient Bio	▪ Objective: Mutual diversification ▪ Dynamic: RPRD to offer pharmacogenomic testing in South Korea ▪ Dynamic: Orient Bio to move into precision medicine
Genome Medical	Fabric Genomics	▪ Objective: Better interpretation of genetic results ▪ Dynamic: Genome Medical's genetic counsellors to use Fabric's newly launched Enterprise clinical genomics platform to interpret patient genetic results
OneOme	Rainbow Genomics	▪ Objective: Furnish OneOme's RightMed pharmacogenomic test together with Rainbow's whole-exome sequencing test services in Hong Kong, Japan and Macau ▪ Dynamic: Rainbow to offer full OneOme RightMed platform to patients and physicians ▪ OneOme has similar arrangements for RightMed inAustralia, Canada and Mexico
Admera Health	Angsana Molecular & Diagnostics Laboratory	▪ Admera gains access to Angsana's physician network in in Singapore, Hong Kong and Malaysia ▪ Deal accompanied by a pair of distribution agreements made by Admera covering Korea and Taiwan (see "Distribution Agreements" below)
Ambry Genetics	NorthShore University HealthSystem	▪ Objective: Genetic testing research ▪ Dynamic: Ambry to provide whole-exome sequencing for 10,000 patients enrolled in NorthShore's Genomic Health Initiative
Morphotek	Fujirebio Diagnostics	▪ Objective: Validate and commercialize CA125 II assay as companion diagnostic for identifying patients who can benefit from Morphotek's investigational ovarian cancer treatment ▪ Dynamic: CA125 II assay to be used on Fujirebio's Lumipulse Instrument System ▪ Fujirebio to get worldwide license to develop, manufacture and commercialize CA125 II as companion diagnostic
Ambry Genetics	FDNA's	▪ Objective: Develop clinical ordering platform ▪ Dynamic: Product integration combining AmbryPort 2.0 platform with FDNA's Face2Gene phenotyping applications

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	**Partner 2**	**Deal Summary**
Variantyx	FDNA	▪ Objective: Develop platform for using genetic variants to develop patient phenotypes ▪ Dynamic: Product integration combining Variantyx's Genomic Intelligence platform with FDNA's Face-2Gene phenotyping applications
DNAnexus	Edico Genome	▪ Objective: Develop platform for whole genome analysis ▪ Dynamic: Product integration of Edico Genome's Dragen Genome Pipeline analysis technology and DNAnexus' cloud-based genome informatics platform
DNAnexus	Saphetor	▪ Objective: Develop platform for genome-based biomarker discovery and interpretation ▪ Dynamic: Product integration leveraging Saphetor's variant analysis software to annotate and classify variants from NGS directly from DNAnexus cloud platform
Qiagen	Clinical Genomics	▪ Objective: Development of colorectal cancer recurrence liquid biopsy ▪ Dynamic: Product integration in which Qiagen's circulating cell-free DNA (ccfDNA) blood-collection tubes is integrated into Clinical Genomics' liquid biopsy test for colorectal cancer recurrence
Qiagen	Angle	▪ Objective: Co-marketing of circulating tumor cell (CTC) technology products ▪ Dynamic: Market Angle's Parsortix system for harvesting CTCs together with Qiagen's liquid biopsy portfolio, including NGS, PCR, single-cell analysis and bioinformatics products
T2 Biosystems	Cidara Therapeutics	▪ Objective: Commercial placement of T2Dx instruments to support clinical trials for Cidara's antifungal CD101s ▪ Dynamic: Create exclusive pricing program to accelerate enrollment in trials evaluating Cidara's echinocandin antifungal CD101 and increase number of hospitals adopting T2's products
Exosome Diagnostics	CareFirst Blue Cross Blue Shield	▪ Objective: Conduct clinical studies that can be used to persuade health plans to cover Exosome's molecular diagnostic products ▪ Dynamic: CareFirst to be Exosome's preferred partner for conducting evidence development studies designed to demonstrate clinical and cost-saving benefits of its tests
Illumina	Advanced Analytical Technologies (AATI)	▪ Objective: Develop streamline platform nucleic acid isolates and prepared libraries analysis ▪ Dynamic: Co-marketing of AATI's Fragment Analyzer automated capillary electrophoresis systems for quality control analysis of nucleic acids with Illumina's NGS workflows ▪ Similar to co-marketing deal for NGS library prep that AATI made with TTP Labtech earlier in 2017
Illumina	Telegraph Hill Partners (venture capital firm)	▪ Objective: Sell Illumina's forensic sequencing technology ▪ Dynamic: Launch of new company called Verogen to be sole provider of (and have global commercial rights to) Illumina's MiSeq FGx sequencing, ForenSeq DNA Signature Prep Kit and ForenSeq Universal Analysis Software ▪ Illumina to provide Verogen with sales and marketing, service and customer support during initial transition period
Illumicare	ARUP Laboratories	▪ Value-based care collaboration ▪ Dynamic: Allow ARUP Labs to offer its MD clients access to Illumicare's Smart Ribbon electronic medical record technology for providing "real-time visibility of the cumulative risk and financial impact of tests and medications being ordered during the course of care"
VolitionRx.	Laboratory Medicine of German Heart Center at Technical University of Munich	▪ Dual Objectives: Validate VolitionRx's Nu.Q assays and advance its efforts to develop clinical trials for lung, pancreatic, prostate, colorectal, breast, and ovarian cancer ▪ Dynamic: 3-year partnership agreement with University's senior physician Stefan Holdenrieder
IBM	JDRF	▪ Objective: Research development of type 1 diabetes (T1D) in children ▪ Dynamic: Combine IBM's computing power with JDRF's research expertise and worldwide connections create an entry point for T1D in field of precision medicine
Tempus	University of California Davis Comprehensive Cancer Center	▪ Objective: Development of personalized medicine cancer treatments ▪ Dynamic: Tempus to perform next-generation sequencing on center patients with pancreatic cancer and hematological malignancies ▪ Latest of Tempus's collaborations with academic centers including University of Chicago, Duke, University of Pennsylvania, Ohio's University Hospitals Seidman Cancer Center and Mayo Clinic
Biocept	University of Texas Southwestern Medical Center	▪ Objective: Non-small cell lung cancer research ▪ Dynamic: Biocept and UT Southwestern research team to do study evaluating former's Target Selector platform for rapid detection of ALK mutations in NSCLC patients

DISTRIBUTION, SALES & MARKETING AGREEMENTS		
Property Owner	**Distributor**	**Deal Summary**
Pathnostics	GenomeDx	■ Products: Pathnostics' Guidance UGx and Guidance PRx tests ■ Territory: U.S. ■ Exclusive
ProAxsis	*Diagenics*	■ Product: ProAxsis's ProteaseTag Active Neutrophil Elastase Immunoassay ■ Territories: Great Britain and Ireland
Admera Health	AllBio Pharma	■ Products: All Admera molecular diagnostic products ■ Territory: Undisclosed although AllBio Pharma is based in Taiwan
Admera Health	Biois	■ Products: All Admera molecular diagnostic products ■ Territory: Undisclosed although Biois is based in South Korea
Baebies	Trivitron's Labsystems Diagnostics	■ Bilateral agreement ■ Labsystems to distribute Baebies' Seeker platform worldwide ■ Baebies to distribute Labsystems' newborn screening products in U.S. after getting regulatory greenlight
Interpace Diagnostics	LabCorp	■ Products: Interpace's ThyGenX and ThyraMIR molecular thyroid cancer diagnosis tests ■ Territory: Worldwide ■ Exclusive ■ 2-year extension of 2015 agreement thru 2019
OmniSeq	LabCorp	■ Products: OmniSeq's Immune Report Card and OmniSeq Comprehensive pan-cancer NGS assays ■ Territory: U.S. ■ Exclusive
Streck	*Biomedical Diagnostics*	■ Products: Streck's cell stabilization and molecular products ■ Territory: BeNeLux ■ Exclusive
Streck	TK Biotech	■ Products: Streck's cell stabilization and molecular products ■ Territory: Poland ■ Streck has inked recent distribution deals in Canada, Austria, Scandinavia, BeNeLux, Switzerland, Slovakia, China, Kuwait, Indonesia, the Philippines, Singapore, Malaysia and New Zealand
Canon BioMedical	Sanbio	■ Products: Canon's research-use-only Novalelle genotyping assays for detecting genetic variations ■ Territory: BeNeLux
Ceres Nanosciences	Innatoss Laboratories	■ Product: Ceres' Nanotrap Lyme Antigen Test ■ Territories: U.K., Austria, BeNeLux, France, Germany and Switzerland ■ Test to be offered as LDT
NantHealth	Asia Genomics	■ Product: NantHealth's GPS Cancer molecular profiling service ■ Territories: Malaysia, Vietnam, Singapore, Thailand and the Philippines ■ Exclusive
LICENSES		
Licensor	**Licensee**	**Deal Summary**
Angle	Queen Mary University of London (QMUL)	■ Property: Angle's Parsortix system for researching cancer patient outcomes ■ QMUL gets option to license exclusively on world-wide basis ■ Angle retains all of its existing intellectual property rights in Parsortix but QMUL gets right to file patents for its findings using Parsortix
Baylor Genetics	Fluidigm	■ Property: NGS library prep assay for detecting cystic fibrosis transmembrane conductance regulator (CFTR) gene ■ Fluidigm gets right to commercialize assay for research use on its Juno automated microfluidic system
SUPPLY, SERVICE & TESTING AGREEMENTS		
Supplier	**Client**	**Deal Summary**
Co-Diagnostics	Medcis Pathlabs India	■ Medcis to buy up to 36,000 of Co-Diagnostics' hepatitis B, hepatitis C, HIV and human papillomavirus tests ■ CoSara Diagnostics, Co-Diagnostics' joint venture, to manufacture and brand tests, and seek all required regulatory approvals ■ Medcis also gets right to buy future products developed by Co-Diagnostics

Company of the Month: Interpace Diagnostics

Question: What do Parsippany, NJ-based Interpace Diagnostics and butter have in common?

Answer: They're both on a roll.

- *July 27:* The molecular lab announces that Cigna will cover its ThyGenX molecular thyroid next-generation sequencing test (which is also covered by Medicare, Aetna and UnitedHeathcare, among others);
- *Aug. 10:* Interpace reports an 8 percent increase in year-over-year second quarter revenues;
- *Aug. 28:* The announced 2-year extension of exclusive thyroid products distribution agreement with LabCorp fuels 8 percent increase in Interpace stock; and
- *Sept. 13:* AMA assigns new CPT code 0018U to ease reimbursement of Interpace's ThyraMir miRNA-based molecular test for indeterminate thyroid nodules.

Runners Up

Other lab companies that had a strong month included:

Myriad Genetics, which scored a pair of significant coverage victories from Medicare (Palmetto) and Aetna for EndoPredict, an assay that uses a 12-gene molecular assessment score combined with tumor size, nodal status and other features to determine if it is medically safe for clinically low-risk breast cancer patients to skip chemotherapy.

Castle Biosciences, which secured coverage for its DecisionDx-UM for assessing uveal melanoma from Aetna.

NanoString Technologies, which announced that Anthem had decided to cover the firm's Prosigna assay, which provides a risk category and number score reflecting a breast cancer patient's 10-year recurrence risks. "Over 95 percent of U.S. patients that are indicated for Prosigna are now covered," according to the company.

Abbott, which secured FDA approval for use of its i-STAT Hematocrit test for *in vitro* quantification of packed red blood cell volume fraction in arterial or venous heparinized whole blood, or in arterial or venous non-anticoagulated whole blood, on the firm's proprietary Alinity platform.

Quest, which announced that its existing low density lipoprotein (LDL) cholesterol tests are using a new calculation that not only improves accuracy but also eliminates the patient's need to fast before being tested. This is the first nonfasting lipid test, the company claims.

Quidel, which secured more favorable terms for its acquisition of Alere's Triage BNP assay business, including a $160 million cut in the purchase price and elimination of previously agreed-to Abbott retention of $50 million worth of distribution rights ensuring Quidel total control over BNP.

Medicare Reimbursement: 4 Molecular Assays Score Big Coverage Wins

Molecular labs continue to gain ground with Medicare securing four key approvals via finalization of Local Coverage Determinations (LCDs) issued by principal contractor Palmetto GBA this spring. All of the determinations take effect Oct. 9.

1. Oncotype DX for Intermediate-Risk Prostate Cancer

Test: Genomic Health's Oncotype DX Genomic Prostate Score (GPS) for prostate cancer risk assessment.

Coverage: GPS, which is currently covered for clinically-low risk men, will also be covered for favorable intermediate-risk prostate cancer under National Comprehensive Cancer Network (NCCN) guidelines. Conditions:

- Testing must be by physicians enrolled in a Palmetto MolDX-approved Certification and Training Registry program; and
- Physicians must monitor for disease progression and report cases of metastasis or prostate cancer deaths in patients that the assay deemed low risk.

Context: The positive coverage decision expands the number of Medicare beneficiaries eligible for the test from 50,000 to 80,000. (See, *LIR* Jan. 6, 2017).

2. AlloSure for Kidney Transplant Rejection Risks

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

Coverage: AlloSure covered for measuring probability of allograft rejection in kidney transplant recipients for whom there's a clinical suspicion of rejection at least two weeks post-transplant. Conditions:

- Patients must be over 18; and
- Physicians must assess active renal allograft rejection probability before ordering.

Context: Medicare contractor Noridian has also issued but not yet finalized a positive LCD for AlloSure.

3. DecisionDx-UM for Uveal Melanoma Prognosis

Test: DecisionDx-UM, Castle Biosciences' test for assessing metastatic risk of uveal melanoma.

Coverage: Test covered for newly diagnosed uveal melanoma patients and to guide oncology surveillance and referral.

Context: Castle announced that Aetna has also decided to cover the test which is also covered by 14 Blue Cross Blue Shield plans (in CA, FL, NJ, NC, MI, MA, WA, OR, AL, AZ, LA, UT, ID and AK)—58 million total recipients.

Guardant Awaits Final Word on Medicare Coverage for Guardant360

Guardant Health was also among the labs receiving a preliminary coverage determination from Palmetto this spring for its Guardant360 lung cancer liquid biopsy. But unlike those other labs mentioned in the story, Guardant is still waiting for the Medicare contractor to finalize the LCD. Coverage would be limited to patients with advanced non-small cell lung cancer, i.e., stage IIIB or higher, and be subjects that vary depending on stage of treatment. The LCD rules out coverage of Guardant360 for repeat testing for therapeutic monitoring and assessment of germline variants.

4. EndoPredict Test to Help Breast Cancer Patients Avoid Chemotherapy

Test: Myriad Genetics's EndoPredict, 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.

Coverage: EndoPredict 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 3 positive nodes and are being considered for adjuvant endocrine therapy.

Context: Other breast cancer prediction molecular assays on the market that have received favorable Medicare coverage determinations from Noridian include:

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

Takeaway: While positive, Medicare coverage for newfangled molecular assays remains piecemeal and frustratingly slow to attain.