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HIGHLIGHTS

TOP OF THE NEWS

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Upcoming Events

Conference:
Lab Institute 2018
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www.labinstitute.com

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

Good news for any of you who slept through December 2017: You didn't miss much—at least as far as blockbuster strategic deals in the clinical laboratory space are concerned.

M&A

In contrast to December 2016, the final month of 2017 was short on new deals with most of the action representing closings of transactions announced earlier in the year, headlined by the Dec. 21 closing of PerkinElmer's $1.3 billion acquisition of Euroimmun, the year's fifth biggest M&A deal. (See page x for an overview analysis of the 2017 Year in Lab M&A.)

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Industry Buzz: 2017—The Year in DX Mergers & Acquisitions

Meh. That word best describes the state of 2017 merger and acquisition activity in the clinical laboratory space, where firms continue to prefer alliance to absorption at a rate of over 3 to 1. But while the M&A year was relatively light in both volume and drama, it was not without its points of interest.

The Abbott Bookends

As it did in 2016, Abbott stole this year's headlines with its bookend acquisitions of St. Jude Medical ($25 billion) in early January and Alere in October. But impactful as they were, these deals were really just consummations of transactions negotiated in 2016.

But one of those closings was anything but routine. The Abbott-Alere merger announced in February 2016 stood on the precipice with the parties poised for litigation by year's end.

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Diagnostic Deals, *from page 1*

One significant piece of new business was the announcement that Genoptix has agreed to acquire Rosetta Genomics for $10 million in cash. The year 2017 was a rough one for Rosetta. After layoffs, divestment of its PersonalizeDx firm less than two years after acquisition and continued threat of Nasdaq delisting for failure to meet the exchange's $1 minimum bid requirement, it probably makes sense for the firm to be absorbed as a wholly owned subsidiary of Genoptix. The deal also makes tons of sense for Genoptix, which acquires Rosetta's RNA-based technology assets.

Impetus for strategic activity in the labs sector is also being supplied by another major M&A deal—Becton Dickinson's planned acquisition of CR Bard.

Meanwhile, the market continues to feel the shakeout from the Abbott-Alere deal of October. Quidel was one of the beneficiaries of the merger, picking up the B-type naturietic peptide (BNP) assay business that Alere had to divest to clear the way for the Abbott merger. But on Nov. 27, Beckman Coulter filed a legal challenge to Quidel's exclusive rights to sell the assay, which runs on Beckman Coulter's analyzers, asking a California federal court to declare its right to sell the assay to its own customers. For its part, Quidel has declared its intention to fight back and defend its exclusive sales rights.

Impetus for strategic activity in the labs sector is also being supplied by another major M&A deal—Becton Dickinson's planned acquisition of CR Bard. In December, BD announced that it has agreed to sell its soft tissue core needle biopsy products to Merit Medical Systems to secure antitrust clearance for the Bard deal.

Strategic Alliances

One of the most significant trends in 2017 alliance-making, namely, collaboration between labs and the biopharma sector, continues to predominate. Notable new examples from late November/early December include:

- A $2.9 billion, 18-month venture between AstraZeneca and Chembio Diagnostics to develop a quantitative, reader-based point-of-care test leveraging the latter's dual-path-platform immunoassay technology; and
- A collaboration between Janssen Pharmaceuticals and Genomic Health to evaluate the effectiveness of the latter's Oncotype DX Genomic Prostate Score in identifying patients who would benefit from prostate cancer drugs in Janssen's R&D pipeline.

Another of 2017's big alliance trends, product integration, was also well represented. For example, two months after announcing integration of its FaceGene NGS phenotyping products with Ambry Genetics' AmbryPort 2.0 clinical ordering system, FDNA announced a similar deal involving testing and interpretation services from PreventionGenetics;

Here's a graphic summary of the key diagnostic deals from late November through December:

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MERGERS, ACQUISITIONS & ASSET SALES		
Acquiring Company	**Target(s)**	**Deal Summary**
PerkinElmer	Euroimmun Medical Laboratory Diagnostics	▪ Price: Approximately $1.3 billion cash ▪ Status: Closing of deal announced in June ▪ Acquisition of Euroimmun, recognized as a global leader in autoimmune testing and emerging force in infectious disease and allergy testing, expands PerkinElmer's reach into autoimmune and allergy diagnostic markets, and enables it to offer "new infectious disease capabilities to customers in China," according to company spokesman
Skyline Medical	Helomics	▪ Price: Undisclosed ▪ Skyline to acquire equity stake of up to 25% in Helomics ▪ In November, Skyline and Helomics partnered on deal to develop new personalized cancer diagnostics using the Helomics D-Chip platform
Genoptix	Rosetta Genomics	▪ Price: $10 million cash, approximately $0.60 per outstanding share to be financed via $1.8 million bridge loan ▪ Status: Expected to close Q1 2018 ▪ Rosetta to become wholly-owned sub of Genoptix
Siemens Healthineers	Fast Track Diagnostics	▪ Price: Undisclosed ▪ Status: Agreement reached with no closing date announced ▪ Siemens acquires over 80 platform-agnostic assays and syndromic panels to its Siemens' Versant kPCR Molecular System test menu ▪ Target to continue operating under FTD name
Quest Diagnostics	Shiel Medical Laboratory (from Fresenius Medical Care)	▪ Price: Undisclosed ▪ Status: Closing of deal announced in October ▪ Deal doesn't include Spectra Labs, Fresenius' dialysis lab services business ▪ Sides also agree to leverage Quest's lab data analytics to identify early-stage chronic kidney disease patients who may benefit from treatment to slow progression to end-stage renal disease
VANC Pharmaceutical	HealthTab	▪ Price: $200,000 (US$157,471) cash paid to HealthTab's vendors, including C$100,000 at closing + balance in 6 later installments ▪ Status: Signed shared purchase agreement to acquire all HealthTab common shares—no closing date announced ▪ HealthTab is a Canadian POC pharmacist platform for cholesterol, triglyceride and other testing
StatLab Medical Products	American MasterTech Scientific	▪ Price: Undisclosed ▪ Status: Closed ▪ Texas-based provider of histology, cytology and immunohistochemistry diagnostic supplies acquires supplier of specialty lab products, including stains for cancer diagnosis
Orig3n	Interleukin Genetics	▪ Price: Undisclosed ▪ Status: Closed ▪ Acquisition, which includes Interleukin's CLIA-certified lab, is culmination of Interleukin's planned asset liquidation announced in July ▪ Orig3n also acquires IP rights to Illustra, Interleukin's controversial genetic test for severe gum disease
Avista Capital Partners	Miraca Holdings	▪ Price: $175.6 million ▪ Status: Closing of deal announced in Sept. ▪ Avista acquires Miraca Life Sciences, which will be owned by new holding company called Symphony Buyer ▪ MLS parent company Miraca Holdings to own 15% of Symphony Buyer's shares
Roche Diagnostics	Viewics	▪ Price: Undisclosed ▪ Status: Closed ▪ Roche acquires privately held lab business analytics company
Merit Medical Systems	Becton Dickinson	▪ Price: Undisclosed ▪ Status: Contingent on closing of BD's acquisition of CR Bard ▪ BD asset sell off is part Bard acquisition ▪ Merit acquires soft tissue core needle biopsy products that BD sells under Achieve Programmable Automatic Biopsy System, Temno Biopsy System and Tru-Cut Biopsy Needles trade names ▪ Merit to also acquire Aspira Pleural Effusion Drainage Kits and Aspira Peritoneal Drainage System currently marketed by Bard

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	**Partner 2**	**Deal Summary**
Chembio Diagnostics	AstraZeneca	▪ Objective: Develop point-of-care diagnostic test to detect undisclosed biomarker ▪ Dynamic: 18-month agreement under which AstraZeneca to provide up to $2.9 million in funding for Chembio to develop quantitative, reader-based POC test leveraging its patented dual-path-platform immunoassay technology
Lucence Diagnostics	AstraZeneca Singapore	▪ Objective: Provide women in Singapore with ovarian cancer better access to BRCA testing ▪ Dynamic: AstraZeneca to subsidize the testing to be performed by Lucence via its clinical lab
Roche Diagnostics	Horizon Discovery	▪ Objective: Develop immunohistochemistry reference standards for oncology assays ▪ Dynamic: Deal leverages previous partnership with Roche sub Ventana Medical Systems to develop cell line derivative material for use as reference standards in diagnosing cancer tissue
Drawbridge Health	Thorne Research	▪ Objective: Improve blood collection tools ▪ Dynamic: Thorne Research and its sub WellnessFX to get access to Drawbridge Health's technology for integrating blood draw, collection and sample stabilization into single device
Ortho Clinical Diagnostics	Sphingotec	▪ Ortho to use Sphingotec's Sphingotest Bio-ADM heart failure immunoassay on its automated Vitros immunodiagnostics and integrated systems
Hummingbird Diagnostics	BGI (previously known as the Beijing Genomics Institute)	▪ Objective: Develop tests for Alzheimer's, Parkinson's and other diseases ▪ Dynamic: Leverage Hummingbird's miRNA database and expertise in sample preparation alongside BGI's BGISEQ sequencer and analysis pipeline
Genomic Health	Janssen Pharmaceuticals	▪ Objective: Evaluate Genomic Health's Oncotype DX Genomic Prostate Score as predictor of response to prostate cancer drugs in Janssen's pipeline ▪ Dynamic: Genomic Health to test samples from studies Janssen is conducting to examine association of GPS results with clinical outcomes
Genomic Health	Cleveland Diagnostics	▪ Objective: Develop prostate cancer tests based on Cleveland Diagnostics' IsoPSA reagents and technology ▪ Dynamic: Genomic Health to initially focus on developing high-PSA reflex test for predicting presence of high-grade cancer before prostate biopsy ▪ Genomic Health gets exclusive global rights to develop and commercialize early- and late-stage cancer diagnostic tests
Agendia	University Hospitals Leuven (Belgium)	▪ Objective: Validate *in vitro* diagnostic kit version of Agendia's MammaPrint and BluePrint breast cancer assays ▪ Dynamic: UZ Leuven to process breast tumor samples from patients in study using NGS-based MammaPrint BluePrint Kit ▪ Agendia to compare results with those from the existing microarray-based MammaPrint test performed at its Amsterdam lab
Agendia	Institut Curie (France)	▪ Objective: Validate in vitro diagnostic kit version of Agendia's MammaPrint and BluePrint breast cancer assays ▪ Dynamic: Agendia to compare results from samples processed at Institute's diagnostics core facility using new NGS kit, to results from existing CE-marked microarray-based test performed at its Amsterdam lab
Biocartis	Amgen	▪ Objective: Develop companion diagnostic assay for Biocartis Idylla RAS biomarker tests ▪ Dynamic: Biocartis to seek FDA premarket approval for Idylla KRAS Mutation Test and Idylla NRAS-BRAF Mutation Test for use as companion diagnostic tests for Amgen's Vectibix (panitumumab)
ExpreS2ion Biotechnologies (Denmark)	Institut VirionSerion (Germany)	▪ Objective: Evaluate new *in vitro* diagnostic candidates produced using ExpreS2 platform ▪ Dynamic: Virion gets access to platform for doing evaluation as well as commercial rights to rights to promote, sell and distribute protein antigens produced via platform
NantHealth	University of California, San Francisco	▪ Objective: Metastatic breast cancer research ▪ Dynamic: UCSF researchers to use NantHealth's GPS Cancer molecular analysis test to conduct study on samples collected by NantHealth
FDNA	PreventionGenetics	▪ Objective: Product integration ▪ Dynamic: PreventionGenetics integrates its testing and interpretation services with FDNA's Face2Gene NGS phenotyping products ▪ Similar to September deal in which FDNA announced integration of Face2Gene with Ambry Genetics' AmbryPort 2.0 clinical ordering system
Biocept	University of California, San Diego	▪ Objective: Clinical validation study of Biocept's Target Selector PD-L1 assay in patients diagnosed with non-small cell lung cancer ▪ Dynamic: UCSD researcher to lead 100-patient trial evaluating assay in NSCLC patients using two antibody clones for PD-L1 detection (28-8 and 22C3)

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	**Partner 2**	**Deal Summary**
AroCell (Sweden)	Green Cross Cell (South Korea)	▪ Objective: Develop AroCell's TK 210 ELISA as complementary test for Green Cross Cell's therapeutic products ▪ Green Cross Cell gets distribution rights to test
Sciex	National University of Singapore's Protein and Proteomics Center	▪ Objective: 2018 launch of proteomics and mass spectrometry training center in Southeast Asia

DISTRIBUTION, SALES & MARKETING AGREEMENTS		
Property Owner	**Distributor**	**Deal Summary**
Eone-Diagnomics Genome Center	Cordlife	▪ Product: Eone's Gen Screen non-invasive prenatal test ▪ Territories: Indonesia and Philippines
BioMérieux	McKesson Medical Surgica	▪ Products: BioMérieux's Vidas BRAHMS PCT, Bact/Alert and Fan Plus Media, ▪ Territory: US ▪ Expansion of previous distribution agreement to US community hospitals
Bio.logis Genetic Information Management	PGS.Holland	▪ Product: Bio.logis' Genetic Information Management Suite ▪ Territories: BeNeLux, Scandinavia and UK
Mesa Biotech	Sekisui Diagnostics	▪ Product: Mesa Biotech point-of-care molecular system for flu A/B ▪ Territories: US and Canada ▪ Exclusive
Thermo Fisher Scientific	Genome Diagnostics	▪ Product: Thermo Fisher's Applied Biosystems QuantStudio real-time PCR systems ▪ Territory: GenDx becomes global reseller ▪ Non-exclusive
Mobidiag	Interlux	▪ Products: Mobidiag's Amplidiag product line ▪ Territory: Estonia ▪ Exclusive
NanoString Technologies	SAM Laboratory (sub of Clearbridge Health)	▪ Products: NanoString's Prosigna breast cancer prognostic gene signature assay ▪ Territories: Singapore, Malaysia, Indonesia and Philippines ▪ Exclusive ▪ Clearbridge to also distribute Prosigna on non-exclusive basis in rest of Asia
MDxHealth	Ferrer	▪ Product: MDx Health's SelectMDx for Prostate Cancer test ▪ Territory: Spain ▪ 5-year exclusive
BioDiscovery	Be Creative Lab	▪ Products: Include BioDiscovery's NxClinical 4.0 software system ▪ Territory: China ▪ Exclusive

LICENSES		
Licensor	**Licensee**	**Deal Summary**
Integrated DNA Technologies	Aldevron	▪ Property: IDT's patented SpyFi Cas9 Nuclease protein mutant ▪ Aldevron to manufacture and distribute protein for research, clinical and commercial uses
ERS Genomics	Charles River Laboratories	▪ Property: ERS Genomics' CRISPR-Cas9 patent ▪ Scope: Global ▪ Non-exclusive
Ncardia	Evotec	▪ Property 1: Ncardia's patented technology for stem cell modeling ▪ Evotec right to use for target discovery, drug efficacy and safety testing immunolabeled long process structures ▪ Scope: Global ▪ Non-exclusive
Agency for Science, Technology, and Research (A*STAR) (Singapore)	Inex Innovations Exchange	▪ Property: A*STAR's non-invasive prenatal testing technology ▪ Exclusive

SUPPLY, SERVICE & TESTING AGREEMENTS		
Supplier/Servicer	**Client**	**Deal Summary**
Helomics	Ariel Precision Medicine	▪ Helomics to serve as the clinical CLIA lab for Ariel's PancreasDx pancreatic disease test
Bluebee (Netherlands)	Agendia	▪ Bluebee to provide data processing services for NGS-based kit version of Agendia's molecular breast cancer diagnostics
Chembio Diagnostics	Bio-Manguinhos	▪ Bio-Manguinhos to buy $8.5 million worth of Chembio's HIV and *Leishmania* POC immunoassays
OraSure Technologies (via its DNAG Genotek sub)	Unnamed consumer genomics firm	▪ $143 million deal to supply Oragene Dx saliva-based DNA collection devices ▪ Multi-year deal is larger than DNAG's $128.2 million in revenue for all of 2016

FDA Watch: Greenlights for NGS Tumor Panels May Augur New Approach to LDT Approvals—Both Product & Pathway

A pair of tumor tests highlights the list of new FDA approvals from mid-November through December, including:

- FoundationOne's CDx (F1CDx) companion diagnostic test for solid tumors; and
- Memorial Sloan Kettering Cancer Center's Integrated Mutation Profiling of Actionable Cancer Targets tumor profiling test assay (MSK-IMPACT).

Of course, FDA approval of next-generation sequencing-based (NGS) personalized medicine cancer assays is always a pretty big deal for the diagnostics community. But these developments may have an even deeper significance to the extent they offer clues on the agency's wider approach to approval of laboratory-developed tests (LDTs) going forward.

The Approved Products

MSK-IMPACT is a 468-gene panel detecting genetic mutations in rare and common cancers. *Data Profile:* According to the agency, the data demonstrated that the assay is highly accurate (over 99%) and capable of detecting a mutation at a range of 2% to 5%. percent to 5 percent). Additionally, the test could detect microsatellite instabilities 92% of the time across multiple cancer types in 175 cases, when compared to traditional detection methods.

F1CDx can detect genetic mutations in 324 genes and two genomic signatures in any solid tumor type. *Data Profile:* The FDA found that the data demonstrated the test's ability to detect select mutation types with 94.6% accuracy. Of course, this isn't the first companion diagnostic the agency has approved. However, rather than match one test to one drug the way all previously approved tests do, F1CDx enables matching of patients with five different tumor types to 15 different approved, targeted treatments, including those for non-small cell lung cancer, melanoma, breast cancer, colorectal cancer, or ovarian cancer.

The Approval Pathways

The story is not just *that* both tests were approved but also how they were approved.

MSK-IMPACT became the first comprehensive tumor-profiling LDT to receive FDA authorization through the de novo premarket review pathway. It had previously been approved by the New York State Department of Health as a laboratory-developed clinical test. The FDA authorized MSK-IMPACT as a Class II, moderate-risk device, which enables subsequent, similar types of tests to use the FDA's less onerous 510(k) clearance pathway.

F1CDx, meanwhile, was approved by the FDA in concert with the CMS under the Parallel Review Program designed to speed up adoption of innovative technologies by allowing for tests to receive FDA approval and immediate Medicare coverage determination simultaneously. The Parallel Review Program is open to certain premarket approval applications for new device technologies that fall within Medicare's Part A or Part B benefit categories. A final coverage decision is expected in the first quarter of 2018, at which time F1CDx will be made commercially available. Analysts say that simultaneous FDA approval and Medicare coverage could also have a positive impact on *private* reimbursement decisions.

Other New FDA Approvals

Meanwhile, here's a rundown of the other key new approvals issued by the FDA in mid-November through December:

NEW FDA APPROVALS

Manufacturer(s)	Product(s)
Foundation Medicine	Approval of FoundationOne CDx (F1CDx), NGS-based genomic profiling test
Memorial Sloan Kettering Cancer Center	Approval of MSK-IMPACT NGS tumor profiling assay
Quidel	Approval of assay to detect Group B Strep using firm's Solana molecular system
Quidel	Approval and CLIA waiver for assay to detect Group A Strep on firm's Sofia 2 fluorescent immunoassay analyzer
Beckman Coulter Diagnostics	Approval of automated Access AMH test for quantitative determination of anti-Müllerian hormone levels
Ortho Clinical Diagnostics	Approval of Vitros Immunodiagnostic Products HIV Combo Reagent Pack and Calibrator for use on Vitros 3600 Immunodiagnostic System
Microgenics	Approval of CEDIA Heroin Metabolite Assay for detecting presence of heroin metabolite in urine
Siemens Healthineers	Approval of: ■ N Latex FLC kappa assay ■ N latex FLC lambda assay ■ N FLC standard SL ■ N FLC Control SL1 and SL2

NEW FDA APPROVALS, *Cont'd.*

Manufacturer(s)	Product(s)
DxNA	Approval of GeneSTAT.MDx Coccidioides test for valley fever
Lia Diagnostics	Approval of Lia Pregnancy Test, making it the first FDA-cleared, flushable, biodegradable pregnancy test, according to the company
Hologic	Approval of Panther Fusion AdV/hMPV/RV respiratory assay for running on firm's Panther Fusion system
Sysmex America	Approval and CLIA waiver for XW-100 Automated Hematology Analyzer, a complete blood cell count test, for use in health care settings such as doctors' offices and clinics
GenePOC	Approval of GenePOC CDiff test detecting the toxin B gene of toxigenic *C. diff* strains directly from stool samples
Grifols	Approval of blood-based alpha-1 antitrypsin (AAT) deficiency test

In December, the FDA granted CLIA waivers to the following test kits:

NEW FDA CLIA WAIVERS

Manufacturer(s)	Product(s)
Alere	Alere, BinaxNOW Influenza A & B Card 2 {With Reader} (Direct Nasal and NP Swabs)
Quidel	Quidel Sofia 2 (Sofia RSV FIA)
Quidel	Quidel Sofia 2 (Sofia Influenza A+B FIA)
Sysmex America	XW-100 Automated Hematology Analyzer

New CE Marks & Global Certifications

Notable European CE certifications:

NEW CE CERTIFICATIONS

Manufacturer(s)	Product(s)
Epigenomics	Approval of Epi proLung blood-based lung cancer test
BGI	Approval of NIFTY cell-free DNA-based noninvasive prenatal test kit for fetal chromosomal aneuploidies on BGISEQ-500 platform
Bio-Rad Laboratories	Approval of QXDx BCR-ABL %IS Kit to detect BCR-ABL gene fusions
Vela Diagnostics	Approval of Sentosa SX Cell-free DNA Kit is now CE marked for running on Sentosa SX101 instrument
Biocartis	Approval of two liquid biopsy tests to detect RAS mutations in circulating tumor DNA from patients with metastatic colorectal cancer: ■ Idylla ctNRAS-BRAF Mutation Test ■ Idylla ctKRAS Mutation Test

Other key international clearances included World Health Organization approval of Atomo Diagnostics' Atomo HIV Self Test, an HIV self-test that is now eligible for procurement by organizations that can access Global Fund and Unitaid resources.

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-November through December:

NEWLY LAUNCHED PRODUCTS & SERVICES

Company(ies)	Product(s)
Thermo Fisher Scientific	Ion Torrent Oncomine Myeloid Research Assay, NGS research panel for simultaneous analysis of 74 genes
Thermo Fisher Scientific	RapidFinder Salmonella Multiplex PCR Detection Workflow for simultaneous detection of *Salmonella typhimurum* and *Salmonella enteriditis*
Thermo Fisher Scientific	Expansion of Invitrogen TrueEdit tool kit
Roche Diagnostics	HyperCap Target Enrichment Portfolio for NGS sample preparation
JN Medsys	New generation of Clarity digital PCR system
Synthego	New CRISPRevolution Gene Knockout Kit (GKO) for all CRISPR researchers
True Health	Respiratory pathogen screening test targeting 21 viral and bacterial pathogens
Trovagene	NextCollect urine collection and DNA preservation kit, for research use only
Promega	Maxwell RSC PureFood Pathogen Kit for PCR-based testing of food pathogens by food safety labs
OmniTier	CompStor Assembly for de novo DNA assembly and reference alignment
Sygnis	TruePrime apoptotic cell-free DNA amplification kit launched under Expedeon brand
Horizon Discovery	New cell line-derived EGFR Multiplex cell-free DNA reference standard
Horizon Discovery	Edit-R CRISPRa reagent platform for CRISPR activation
Cyclica	Ligand Express cloud-based proteome screening platform
OncoDNA	OncoSelect assay for circulating tumor DNA in blood samples from non-small cell lung, colon or breast cancer patients
Epic Sciences	Single-cell profiling panel for metastatic breast cancer
Sonora Quest Laboratories	NGS assay for solid tumors targeting 52 genes based on ThermoFisher Scientific Oncomine Focus Assay
Edico Genome	Dragen Clinical Genomics Information System, software to help labs develop sequencing-based tests
Circulogene	Microsatellite instability biomarker testing for use by oncologists and pathologists to identify patients eligible for treatment with Keytruda or Opdivo for different types of cancer
InSource Diagnostic	ToxLok for verification of urine-based drug tests with a buccal swab
IQuity	IsolateIBS-IBD blood-based test for identification of irritable bowel syndrome or inflammatory bowel disease
Canopy Biosciences	CRISPR Complete Gene Editing Kits for using CRISPR-Cas9 system to perform gene editing research experiments

Industry Buzz: 2017—The Year in DX Mergers & Acquisitions, *from page 1*

After months of posturing, the parties announced in mid-April that the on-again off-again deal was back on again. In addition to dropping their lawsuits, both sides agreed to new terms essentially giving Abbott a discount to compensate for the erosion in equity value that Alere incurred since the original deal was announced by cutting the purchase price to $5.8 billion.

Both sides also had to divest strategic assets to gain regulatory approval for the merger with Alere selling its triage MeterPro and BNP (B-type Naturietic Peptide) businesses to Quidel for $680 million and its Epocal point-of-care blood diagnostics unit to Siemens Healthineers for an undisclosed price.

Abbott and Thermo Fisher dominate the headlines but outsider Minolta may have made the year's biggest splash

Thermo Fisher Gobbles Up Patheon

In terms of dollar volume, Thermo Fisher's $7.2 billion purchase of contract development and manufacturing organization (CDMO) Patheon in September was the year's biggest M&A deal (other than the $25 billion St. Jude deal which closed on Jan. 4). Acquisition of the North Carolina-based provider of drug development support for pharmaceutical firms, secures Thermo Fisher access to the $40 billion CDMO market and create $120 million in synergies ($90 million in cost and $30 million in revenues synergies). Thermo Fisher absorbed Patheon's 9,000 employees and $1.9 billion in annual revenues into its Laboratory Products and Services division.

The Didn't-See-That-One-Coming Award

In perhaps the most surprising—and intriguing—M&A deal of the year, Konica Minolta plunked down $1 billion in cash for genetic testing firm Ambry Genetics. Almost overnight, the Japanese technology giant known for its business products became a major player in the global precision medicine market and acquiring a vehicle for commercializing high-sensitivity tissue immunostaining technology for clinical pathology and pharmaceutical trials.

The Other Billion-Dollar Deals

The only other nine-figure M&A DX deals to close in 2017 were:

- Grifols' $1.85 billion buyout of Hologic's blood screening assets, a move that seems to have worked out for both sides by goosing Grifols' revenues blood screening revenues 7% while leaving Hologic, its former partner in the realm, free to concentrate on its core women's diagnostics business;
- PerkinElmer's $1.3 billion cash acquisition of Euroimmun Medical Laboratory Diagnostics, which establishes PKE as a global leader in autoimmune testing and bolstering its position as a provider in infectious disease and allergy testing in China and other leading markets; and
- LabCorp's purchase of UK contract research organization Chiltern for $1.2 billion, creating a CRO unit of 20,000+ employees and strengthening its Covance business in the biopharma market.

LabCorp v. Quest

As usual, LabCorp and rival Quest Diagnostics were among the most active players. But while the two have been waging a kind of M&A arms race for years, LabCorp flipped the script in 2017 by acquiring Mt. Sinai Health System outpatient labs and the ownership interests of Washington-based Pathology Medical Laboratories, LLC (PAML) in five different outreach lab joint ventures (Colorado Laboratory Services, Kentucky Laboratory Services, MountainStar Clinical Laboratories, PACLAB Network Laboratories and Tri-Cities Laboratory). In the past, LabCorp has focused on acquiring specialty labs to bolster the sophistication of its product lines, while the strategy of acquiring health system outreach labs has largely been Quest's *modus operandi*. Sure enough, Quest made seven more such acquisitions during the year, including Cleveland HeartLab, MedFusion, Cape Cod Health Care, to name a few.

Other firms with the largest number of purchases during the year included:

- LabCorp, which in addition to the above noted PAML, Mt. Sinai and Chiltern deals acquired health and nutrition test firm ChromaDex;
- Thermo Fisher Scientific, which in addition to the big Patheon acquisition, acquired a trio of smaller firms including Linkage BioSciences, Core Informatics and Finesse Solutions;
- Invitae, which acquired AltaVoice, CombiMatrix, Good Start Genetics and software maker Ommdom; and
- Bruker, which a few months after announcing the acquisitions of SCiLS and InVivo Biotech Services on the same day, picked up Merlin.

NEW FDA APPROVALS

Rank	Acquiring Company	Target Company	Price	Closing Date
1	Abbott	St. Jude Medical	$25 billion	January
2	Thermo Fisher Scientific	Patheon	$7.2 billion	September
3	Abbott	Alere	$5.8 billion	October
4	Grifols	Hologic (blood screening business)	$1.85 billion	February
5	PerkinElmer	Euroimmun Medical Laboratory Diagnostics	$1.3 billion	December
6	LabCorp	Chiltern	$1.2 billion	September
7	Konica Minolta	Ambry Genetics	$1 billion	November
8	Quidel	Alere's triage MeterPro and B-type Naturietic Peptide (BNP) assay businesses	$680 million	October
9	Bruker	InVivo Biotech Services	$276 million	January
10	Thermo Fisher Scientific	Finesse Solutions	$220 million	February

Note: Only includes deals in which price and other financial terms were disclosed.

PAMA-geddon: Lab Industry Asks Court to Stop New Medicare Fee Schedule

With CMS refusing to back down, the lab industry has escalated the dispute and asked a U.S. District Court to step in and prevent enforcement of the 2018 PAMA-inspired Part B Clinical Lab Fee Schedule (CLFS).

The Claims

The Dec. 11 lawsuit filed by the American Clinical Laboratory Association asserts three basic claims:

1. CMS exceeded its PAMA statutory authority to determine market prices by deliberately excluding hospital labs, which represent the vast majority of the lab market;
2. Not counting hospital labs was an unreasonable interpretation of PAMA—specifically the term "applicable laboratories"; and
3. The CMS pricing formula is "arbitrary, capricious" and an "abuse of discretion."

What ACLA Wants the Court to Do

Rather than award money damages, the ACLA wants the court to take injunctive action to resolve the problem by:

- Barring CMS from putting the 2018 CLFS into effect; and
- Ordering CMS to obey PAMA by revising its pricing formula to include hospital labs as "applicable laboratories" for purposes of calculating market rates.