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HIGHLIGHTS

Upcoming Events

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

After a brief summer lull, strategic deal making ramped up in September, especially in alliance making where volume nearly doubled last month's levels. Here's an overview of the long-term trends and key deals from late August through the third week of September.

Mergers & Acquisitions and Asset Sales

The M&A highlight of the month was the closing of Agilent's acquisition of privately held life science instrumentation

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Industry Buzz: Cologuard's Wild September Ride

The month of September has been a rollercoaster for a product that has in many ways become the face of the consumer genetic testing market, Exact Sciences' Cologuard.

The Growth of Cologuard

The first stool multi-target stool DNA test (mtSDNA) for colorectal cancer screening, Cologuard has enjoyed great commercial success since its 2014 launch. The test is covered by Medicare and most private insurers. Nearly 174,000 doctors have ordered the test, including 142,000 primary care physicians. Each week, 900 new doctors join the list of orderers each week. According to Exact Sciences' most recent earnings report, Cologuard rakes in average revenues of $479 per test at an average cost of $123. It now accounts for 6% of the total U.S. colorectal cancer testing market.

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Diagnostic Deals, *from page 1*

manufacturer BioTek for $1.7 billion. The deal, which was announced in July, boosts Agilent's position in the immune-oncology and immunotherapy markets, albeit at a higher valuation than what the firm had previously pursued. Meanwhile, the other Dx blockbuster announced in July, the $2.8 billion acquisition of Genomic Health by rival genetic cancer testing firm Exact Sciences, remains on track for a late 2019 closing.

But perhaps the most noteworthy M&A theme was role reversal, with big lab companies acting as sellers rather than buyers. Thus, two different firms made strategic divestments during the period, including:

- Natera, which sold off its Evercord cord blood and tissue banking business to California Life Sciences Company CBR (Cord Blood Registry) to focus on its core genetic reproductive health, oncology and organ transplant testing operations; and
- OraSure Technologies which sold its cryosurgical systems operations to CryoConcepts so it could give full attention to its core infectious disease and molecular solutions businesses.

In addition to the deals listed below, Illumina announced that it had received an unsolicited "mini-tender offer" from investment firm TRC Capital for up to 500,000 shares of Illumina common stock at a cash price of $268.60 per share. Illumina recommended that shareholders decline the offer, which remains open until midnight Oct. 2. TRC has made similar offers for other companies seeking to acquire just enough of an equity stake to stay below the SEC tender offer disclosure requirement threshold, the Illumina board noted.

The other notable M&A deal not listed in the table is the newly announced merger of Cardea Bio and Nanosens Innovations, the companies that teamed up to create a CRISPR-Cas9-based biosensor diagnostic device using a CRISPR-Chip transistor. The plan is for Nanosens to become a Cardea subsidiary with the new firm selling CRISPR-Chip-based products under the Nanosens brand name.

Strategic Alliances

Volume-wise, September was the year's most active month of strategic alliance deal making. Among the most intriguing collaborations was the pairing of Quest Diagnostics with data analysis firm hc1 to launch a new service called the Quest Lab Stewardship to help health systems avoid over- and under-ordering of lab tests. By turning the lemons of intense payor scrutiny over test ordering into the lemonade of utilization management based on testing results, this deal highlights the needs of labs to leverage their testing data to evolve their businesses.

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Here's a summary of key diagnostic deals announced from late August through the third week of September:

MERGERS, ACQUISITIONS & ASSET SALES		
Acquiring Company	**Target(s)**	**Deal Summary**
Exact Sciences	Genomic Health	• Price: $2.8 billion in cash and stock • Status: Expected to close by end of 2019 • Genomic Health common shareholders to get per share price of $27.50 in cash and $44.50 in shares of Exact stock, subject to 10% collar based on Exact's volume-weighted average price for 45 trading days ending July 26 • Create cancer DX megafirm that unites Exact's Cologuard with Genomic Health's Oncotype DX
OpGen	Curetis GMbH	• Price: Curetis to receive 2,662,564 new common shares of OpGen (73% stake) based on $24 million valuation of combined business with current OpGen holders keeping remaining 27% equity share • Status: Expected to close in early 2020 • Curetis to become wholly owned subsidiary of OpGen to create transatlantic, US-based, Nasdaq-listed company with a commercial-stage molecular diagnostics and bioinformatics franchise and pipeline focusing on infectious diseases and antimicrobial resistance
Agilent Technologies	BioTek Instruments	• Price: $1.17 billion • Status: Closed • Acquisition of privately held life science instrumentation manufacturer expands Agilent's presence in cell analysis, immuno-oncology and immunotherapy • Agilent expects BioTek to contribute $20 million to $25 million to 4Q revenues with no material impact on EPS for quarter
CBR (Cord Blood Registry)	Natera	• Price: Undisclosed • Status: No closing date announced • Natera sells its Evercord cord blood and tissue banking business to focus on core genetic testing business in reproductive health, oncology and organ transplantation
OncoCyte	Razor Genomics	• Price: $10 million in cash upfront for 25% of Razor's outstanding equity + $1 million milestone associated with recent positive CMS coverage decision for Razor test assessing risk in early-stage lung cancer patients after surgery • Status: Initial closing expected in Sept. • Razor to use $4 million from initial $10 million payment to support supplemental clinical trial of test • Razor shareholders eligible for additional $10 million in cash and/or $5 million in OncoCyte common stock upon achievement of clinical trial milestones • OncoCyte to use Razor test as predicate in seeking Medicare coverage for its own DetermaVu assay

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MERGERS, ACQUISITIONS & ASSET SALES		
Acquiring Company	**Target(s)**	**Deal Summary**
MyHeritage	River Road Bio	• Price: Undisclosed • Status: Closed • Israeli consumer genomics firm acquires owner of Promethease + SNPedia • MyHeritage to offer Promethease free of charge through end of this year + maintain SNPedia as a free resource for academic + non-profit users
CellaVision	RAL Diagnostics	• Price: $27.7 million • Status: Expected to close in fall 2019 • Acquisition of sample preparation firm to bolster CellaVision's sample prep services for hematology, pathology, cytology + microbiology
ViVitro Labs	ProtomedLabs SASU	• Price: Undisclosed • Status: Closed • Cardiovascular test equipment + medical device testing lab merge operations under ViVitro Labs name
CareDx	XynManagement	• Price: Undisclosed • Status: Closed • CareDx acquires provider of software to simplify transplant quality tracking + waitlist management
PreCheck Health Services	LD Technology + Medical Screening	• Price: $5 million in cash upfront + deferred payment of $7 million in cash + $3 million in stock within 12 months • Status: No closing date announced • Acquisition of medical device firms boosts PreCheck's point-of-care screening capabilities
CryoConcepts	OraSure Technologies	• Price: $12 million cash • Status: Closed • OraSure sells off its cryosurgical systems business to focus on its core molecular solutions + infectious disease businesses
Inex Innovations and Exchange	Nova Satra Dx	• Price: Deal valued at $72 million • Status: Closed • Merger to form new company, called Inex Innovate, aiming to introduce new tests for ovarian cancer and breast cancer in Asian women by 2020
Progenity	Medimetrics	• Price: Undisclosed • Status: Closed • Progenity acquires Medimetrics' portfolio of patents for ingestible device technologies
Thermo Fisher Scientific (TF)	Eli Lilly and Company	• Objective: Develop companion diagnostic test for Lilly's RET kinase inhibitor, LOXO-292 • Dynamic: Use TF's Oncomine Dx Target test to identify non-small cell lung cancer + thyroid cancer patients with RET alterations who might benefit from LOXO-292 • TF to seek FDA supplemental premarket approval broadening clinical claims of Oncomine Dx Target • TF to get global commercial rights to new CDx test

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	**Partner(s) 2+**	**Deal Summary**
Thermo Fisher Scientific	Cedars-Sinai	• Objective: Develop liquid chromatography mass spectrometry workflows for clinical research • Dynamic: Create data acquisition strategies for global plasma protein profiling + peptide selective reaction monitoring (SRM) assays for analyzing plasma with or without enrichment • Use TF's new triple quadrupole mass spectrometers for large quantitation assays to assess targeted protein workflows in a CLIA environment
Illumina	Adaptive Biotechnologies	• Objective: Develop test kits for Adaptive's ClonoSeq + ImmunoSeq Dx NGS tests to run on Illumina's NextSeq 550Dx system • Dynamic: Under 5-year non-exclusive partnership, Adaptive to seek regulatory approval for + commercialize kits • Illumina to develop custom software for using kits on NextSeq instruments + exclusively license software to Adaptive Combine NeuroFlow's IntegrateHealth platform with Genomind's Professional PGx Express genetic testing service so that physicians can use former to administer latter + provide test results to patients • Adaptive to give Illumina 2 technology access milestone payments for software development + tiered revenue share payments ranging from a low to mid-single digit percentage of kits' net sales
Foundation Medicine	Natera	• Objective: Develop + commercialize personalized circulating tumor DNA monitoring assays for biopharma + clinical customers who order FoundationOne CDx • Dynamic: Use FoundationOne CDx test as baseline to define unique variants that codeveloped liquid biopsy assays will monitor • Foundation holds option to expand partnership to its FoundationOne Liquid or FoundationOne Heme tests as baseline for monitoring assays • Foundation gets exclusive right to commercialize assays • Foundation to pay Natera roughly $13 million in upfront licensing fees + prepaid revenues, as well as roughly $32 million in future minimum annual + milestone payments • Revenues to be shared
CareDx	NanoString Technologies	• Objective: Develop gene expression profiling test called HistoMap to identify allograft rejection in transplant biopsy tissue • Dynamic: Combine CareDx's transplant registries + expertise with NanoString's nCounter platform + newly launched Human Organ Transplant panel
Quest Diagnostics	hc1	• Objective: Provide new Quest Lab Stewardship service to help health systems avoid ordering too many or too few tests • Dynamic: Service integrates with electronic medical record to guide doctors as they order tests, creates a systemwide set of tests + analyzes utilization trends

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Diagnostic Deals, *from page 5*

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	**Partner(s) 2+**	**Deal Summary**
Coriell Life Sciences (CLS)	KPMG	• Objective: Provide pharmacogenomics data to clinicians at the point of care • Dynamic: Thermo Fisher Scientific to contribute genetic analysis technology + clinical decision support content • CLS to offer its Enterprise PGx platform system, backed by TF data + team of pharmacists, to assess genetic risks related to specific patients' prescribed medications + link that information to an institution's EHR system • KPMG's clinical intelligence platform to analyze information to help clinicians develop treatment plans for patients
Agilent	Mobilion	• Objective: Implement Mobilion's SLIM (structures for lossless ion manipulation) ion mobility system on Agilent's QTOF mass spectrometers • Dynamic: Beta model of system to be available in 2020 with commercial launch slated for 2021
Blueprint Genetics	Archimedlife Medical Laboratory	• Objective: Provide biochemical testing for rare diseases in North America • Dynamic: Blueprint to license Archimedlife's technology + tests to offer biochemical testing at its Seattle lab, which also provides NGS genetic testing, with the combined testing services to be available in early 2020
Menarini Silicon Biosystems	BlueBee	• Objective: Develop cloud-based platform for processing NGS data from liquid biopsy + formalin-fixed paraffin embedded (FFPE) tissue analysis • Dynamic: Platform, called MSBiosuite, automates processing of raw sequencing data generated with Menarini's Ampli1 kit for single circulating tumor cells + DEPArray kit for FFPE tissue analysis
Celsius Therapeutics	Parker Institute for Cancer Immunotherapy + Institut Gustave Roussy (France) + University Health Network (UHN) (Toronto)	• Objective: Discover new molecular mechanisms + targets for drug discovery • Dynamic: Use Celsius' single-cell genomics platform to test tissue samples from cancer patients receiving immune checkpoint inhibitor treatment as part of 3 studies focusing on triple-negative breast cancer (Parker), bladder cancer (Gustave Roussy) + kidney cancer (UHN)
Novigenix	BioLizard	• Objective: Develop artificial intelligence-based algorithm to support transition of Novogenix's Colox immuno-transcriptomic RT-PCR product onto a new LITOseek system • Dynamic: BioLizard to create algorithm which Novigenix will also use for other products under development
Adaptive Biotechnologies	Amgen	• Objective: Enable Amgen to use Adaptive's ClonoSeq assay to develop blood cancer therapies • Dynamic: Over 4-year agreement, Amgen will pay Adaptive annual development fees + milestones payments in exchange for use of ClonoSeq test

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	**Partner(s) 2+**	**Deal Summary**
LunaPBC	Medfusion	• Objective: Enable users of LunaPBC's LunaDNA genomic data-sharing platform to access health information in their EHRs • Dynamic: Leverage Medfusion's Patient Data application program interfaces (APIs) to provide users access to lab results, recent diagnoses + other EHR information in the LunaDNA platform
Fulgent Genetics	PWNHealth	• Objective: Provide telehealth oversight for Fulgent's newly launched Picture Genetics line of consumer genetic tests • Dynamic: Telehealth firm PWNHealth to provide physician review + genetic counseling for tests
Interpace BioPharma (subsidiary of Interpace Diagnostics)	Genecast Biotechnology	• Objective: Develop + commercialize translational studies +clinical trial solutions to biotech + pharma companies • Dynamic: Interpace to perform services worldwide except in China, where Beijing-based Genecast will provide services
Sano Genetics	GenePlaza	• Objective: Create app for linking users of direct-to-consumer (DTC) genetic tests with clinical trials + other research programs • Dynamic: GenePlaza to offer app enabling its customers to review + opt into research projects via Sano's platform
Arbor Biosciences	Medicinal Genomics (MGC)	• Objective: Develop + commercialize new genotyping panel for cannabis • Dynamic: Perform genetic testing + create cannabis genome knowledge bank to generate a panel for analyzing unique genetic signatures in cannabis strains
Personalis	Invectys	• Objective: Facilitate biomarker discovery in chronic lymphocytic leukemia patients participating in a clinical trial • Dynamic: Personalis to analyze samples from patients enrolled in a Phase II trial assessing the efficacy of Invectys' INVAC-1 alone or in combination with tyrosine kinase inhibitor ibrutinib (marketed by Janssen and Imbruvica)
Bioloidics	Agency for Science, Technology and Research's (A*STAR) Genome Institute of Singapore	• Objective: Develop circulating tumor cell assay to assess minimal residual disease + predict relapse in women with surgically-treated breast cancer • Dynamic: Biolidics to use its ClearCell FX1 technology in the hopes of creating a liquid biopsy platform for early cancer detection
Genmab	Tempus	• Objective: Use artificial intelligence to discover oncology biomarkers + drug targets • Dynamic: Expansion of previous collaboration under which Genmab to identify research projects in which Tempus' sequencing + bioinformatics technology can be used • Genmab to develop + commercialize resulting products + pay Tempus milestone + royalty payments
Abionic	Genentech (part of Roche)	• Objective: Develop + distribute Abionic's asthma test panel in US • Dynamic: Abionic to lead development process + Genentech to pay the clinical + regulatory costs
Veravas	True Diagnostics	• Objective: Commercialize Veravas' VeraTest Biotin for detecting biotin interference in diagnostic tests • Dynamic: New test combines use of True Diagnostics' screening technology and platform with Veravas' nanomagnetic particle technology for removing biotin interferences

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Diagnostic Deals, *from page 7*

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	**Partner(s) 2+**	**Deal Summary**
Fluidigm	Icahn School of Medicine at Mount Sinai	• Objective: Develop epigenetic signatures to identify exposure to weapons of mass destruction • Dynamic: Under aegis of US DoD's Defense Advanced Research Projects Agency (DARPA) Epigenetic Characterization + Observation (ECHO) program
Freenome	ADC Therapeutics	• Objective: Discover biomarkers for use in new cancer drug development • Dynamic: Use Freenome's multiomics platform for early cancer detection to identify patients likely to respond to treatment with ADC's antibody drug conjugate loncastuximab tesirine (ADCT-402)
DISTRIBUTION, SALES & MARKETING AGREEMENTS		
Product Owner	**Distributor**	**Deal Summary**
IsoPlexis	BioStream	• Products: IsoPlexis' IsoCode + IsoLight single-cell protein analysis products • Territory: Japan • Exclusive
Todos Medical	HWH World	• Products: Todos' TM-B1 + TM-B2 early breast cancer detection blood tests • Territory: US, Canada, Singapore, Malaysia, the Philippines, Vietnam, Thailand, Indonesia, South Korea, Hong Kong, China
Todos Medical	Orot[+]	• Products: Todos' TM-B1 + TM-B2 early breast cancer detection blood tests • Territory: Japan
Qiagen	ViroGates	• Products: Qiagen's aLF lateral flow test reader • Territory: Europe • Non-exclusive
LICENSES		
Licensor	**Licensee**	**Deal Summary**
Cambridge Enterprise	PredictImmune	• Expansion of worldwide licensing agreement to give PredictImmune first refusal rights to Cambridge technology to predict disease outcome for systemic lupus erythematosus as a follow-on disease • Previous deal covered technology to predict disease outcome in relapsing-remitting autoimmune + inflammatory disease, specifically for inflammatory bowel disease, including Crohn's disease + ulcerative colitis
Caribou Biosciences	Oxford Nanopore Technologies	• ONT licenses Caribou's foundational CRISPR-Cas9 patents for targeted nanopore sequencing which it plans to use for mediated enrichment of DNA targets for nanopore sequencing
Co-Diagnostics	LGC Biosearch Technologies	• Expansion of current licensing agreement allowing LGC to use CoPrimer PCR technology for additional undisclosed research applications not covered in previous deal

SUPPLY, SERVICE & TESTING AGREEMENTS		
Supplier/Servicer	**Client/User**	**Deal Summary**
Uman Diagnostics (Quanterix subsidiary)	Bio-Techne	• Supply antibodies to Bio-Techne for use on its Ella immunoassay platform for quantification of neurofilament light (Nf-L)
NEW CLINICAL STUDIES		
DX Partner	Other Partner(s)	Description of Study
Exosome Sciences	Hoag Memorial Hospital Presbyterian	• Study to identify + characterize early disease biomarkers for cancer diagnostics, progression + treatment resistance
Biovica	SWOG Cancer Research Network	• Evaluate clinical benefit of Biovica's DiviTum immunoassay using blood samples from women with metastatic hormone receptor-positive breast cancer
Myriad Genetics	University of Leeds Center for Personalized Medicine and Health	• Evaluate clinical utility of Myriad's Prolaris prostate cancer test
Mologic	University College London Hospitals	• Clinical trial evaluating value of Mologic's point-of-care diagnostic test for early detection of sepsis

FDA Watch: New NGS Data Guidance May Ease Antiviral Drugs & Companion Test Approvals

A new FDA Technical Specifications document (Tech Doc) lists recommendations for sponsors on use of next generation sequencing data to secure approval of new antiviral drugs and related diagnostic tests providing crucial guidance on six key issues.

1. Acceptable NGS Platforms: The Tech Doc says the agency will accept nucleotide sequencing data generated from most standard NGS platforms as long as the sponsor submits:

- The appropriate details for the sequencing platform;
- The protocols used for sample preparation;
- The raw NGS data in fastq format; and
- The methods used to analyze the data.

2. Information about NGS Protocol: Sponsors should submit a detailed NGS protocol that includes six design elements:

- A description of the subjects, study time points and sample matrices to be analyzed;
- A description of the NGS platform and all associated performance characteristics;
- Target gene region name(s) and size(s) to be analyzed;
- A description of the general analysis strategy;

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New NGS Data Guidance May Ease Antiviral Drugs & Companion Test Approvals, *from page 9*

- The coverage level to be attempted; and
- A description of the approach used to identify, filter or process sequencing errors.

3. Frequency Tables: Sponsors should provide a frequency table reporting all amino acid substitutions that differ from baseline at frequencies greater than or equal to 1%.

4. Sample Preparation Information: The Tech Doc calls on sponsors to list their methods for:

- Extracting nucleic acids from samples;
- Purifying viral sequences from contaminating background nucleic acids;
- Concentrating viral nucleic acids, including the estimated target copy number input for reverse transcription polymerase chain reaction (RT-PCR) (viral RNA) or PCR (viral DNA) reactions for each sample;
- Denaturing secondary structure;
- Generating double stranded DNA (dsDNA), including a description of the primers;
- Purifying dsDNA for sequencing;
- NGS library preparation; and
- Adding barcodes for multiplexing (if applicable).

5. Information about Data Analysis & Reporting Results: Submissions of sequence data must include a thorough description of the analysis pipeline used to analyze the sequencing dataset and the raw sequence information, including:

- Summary statistics for each sequence run, including total number of reads sequenced per sequence run, quality scores and average length of reads;
- A description of how sequence barcodes were processed;
- Contig and mapping reports—the Tech Doc recommends two data analysis approaches and establishes standards for each: i. mapping of short reads to a reference sequence; or ii. de novo assembly of short reads to assemble contigs.

6. Acceptable Data File Types: The Tech Doc calls on sponsors to provide all raw NGS data from each sequence run in the fastq format, which may also include an assembled read mapping in .fas, .ace, .sam, or .bam formats along with the appropriate reference sequences and accession numbers used for any reference mappings.

Here's a look at other new product approvals announced from late August through late September:

NEW FDA APPROVALS

Manufacturer(s)	Product(s)
Exact Sciences	Expanded clearance for Cologuard DNA-based colorectal cancer screening test in average-risk people age 45 and older (as opposed to previous clearance for people age 50 and over)
BioMérieux	Clearance for Vitek 2 AST-Gram Negative Eravacycline assay for antimicrobial susceptibility testing of Gram-negative bacilli, running on the firm's Vitek 2 and Vitek 2 Compact systems
BioMérieux	Clearance for ETest Imipenem/Relebactam test to determine minimum inhibitory concentration of Imipenem/Relebactam, a carbapenem-β-lactamase inhibitor combination, against Citrobacter freundii, Enterobacter cloacae, Escherichia coli, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae and Pseudomonas aeruginosa
Healthy.io	Clearance for smartphone-based albumin-to-creatinine ratio (ACR) test to diagnose chronic kidney disease
Qiagen	Clearance for Therascreen PIK3CA RGQ PCR Kit as companion diagnostic to identify advanced breast cancer patients with PIK3CA mutations likely to respond to Novartis' Piqray (alpelisib)
Roche Diagnostics	Clearance for cobas Babesia whole-blood test for screening blood donations
Roche Diagnostics	Clearance for Cobas Pro Integrated Solutions
Roche Diagnostics	Clearance for Elecsys Anti-HAV II test to detect total antibodies (IgG and IgM) to hepatitis A virus
Siemens Healthineers	Clearance for Advia Centaur Testosterone II assay to detect total testosterone run on firm's Advia Centaur XP system
Siemens Healthineers	Clearance for the Advia Centaur SHBG immunoassay run on Advia Centaur XP system to measure sex hormone-binding globulin (SHBG) used to diagnose androgen disorders
Axis-Shield Diagnostics	Clearance for received clearance for Advia Centaur Erythropoietin assay to diagnose anemias and polycythemias run on Siemens Advia Centaur XP system
Grifols	Clearance for QNext fully automated random-access instrument to perform hemostasis testing by detecting changes in optical density
Fujirebio Diagnostics	Clearance for Lumipulse G Whole PTH chemiluminescent enzyme immunoassay to measure parathyroid hormone levels during differential diagnosis of hypercalcemia and hypocalcemia resulting from disorders of calcium metabolism
Check-Points	Clearance for BD Max Check-Points CPO Assay run on Becton Dickinson BD Max System
Healstone Biotech	Clearance for Accurate Multi Panel Drug Urine Test Cup lateral flow immunochromatographic assay for detecting a combination of two to 15 drugs of abuse
Laboratory for Advanced Medicine	Breakthrough device designation for liquid biopsy blood test to detect liver cancer at Stage I
Prescient Metabiomics	Breakthrough device designation for LifeKit Prevent Colorectal Neoplasia Test for non-invasive detection of precancerous polyps and early-stage carcinomas
Drawbridge Health	510(k) clearance for OneDraw A1C Test System, which includes a blood collection device and HbA1c test

Cologuard's Wild September Ride, *from page 1*

The Downs: New CMS Report Casts Doubt on Cologuard

But on Sept. 4, the giddiness was tempered with the release of a new CMS-sponsored research report finding Cologuard "less effective and considerably more costly" than alternatives. "At its current reimbursement rate, triennial mtSDNA testing . . . is an inefficient screening option," according to the paper published in the Sept. 4, 2019, issue of PLOS ONE.

Exact blasted the report for understating Cologuard's value proposition by employing unrealistic assumptions, such as adherence rates (i.e., 100% adherence, or relative adherence over a fairly narrow range) for screening, follow-up and surveillance procedures." But news of the report sent Exact Sciences shares sharply downward. Worse, the report came on the eve of a crucial decision from the U.S. Preventive Services Task Force (USPSTF) on whether to recommend mtSDNA colorectal cancer screening.

The Ups: FDA Expands Cologuard Label Clearance

But on Sept. 23, less than three weeks after the CMS-sponsored report, the mood turned completely around again when Exact Sciences announced that the FDA had widened its approval for Cologuard to include people age 45 and older, as opposed to the previous approval for people age 50 and older. The clearance, which came a year before the company expected, adds 19 million potential users to Cologuard's target market. It also greatly improves the prospects for thumbs-up from the USPSTF decision on mtSDNA colorectal cancer screening.