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LABORATORY INDUSTRY REPORT™

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HIGHLIGHTS

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Upcoming Events

Lab Leadership Summit
Friday, April 27, 2018
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Emerging Tests: Medicare to Cover Next Gen-Sequencing Tests for Advanced Cancer

In the PAMA era, there are two salient trends in Medicare Part B lab reimbursements:

- Sharply lower prices for traditional tests; and
- Wider coverage of newly emerging tests, including some that the FDA has not yet approved.

The second trend continued on March 16, when CMS finalized its draft National Coverage determination (NCD) expanding Medicare coverage of next-generation sequencing (NGS) cancer panels.

Continued on page 2

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

The strategic slowdown in the diagnostics sector continues. Late February to March was relatively light in both deal volume and value, especially compared to the same period in 2017. As usual, the impetus for the activity that did occur was supplied by the molecular, genetics and innovative segments of the market.

M&A

On March 9, Danaher announced that it had inked a definitive agreement to acquire privately held genomics firm Integrated DNA Technologies (IDT). Although the price was not disclosed, sources estimate the value of the deal in the neighborhood of $1.9 billion—coincidentally, the same price as 2018's first billion-dollar deal, Roche's purchase of oncology EHR vendor Flatiron Health announced last month. The IDT acquisition comes less than two years after Danaher's $4 billion purchase of Cepheid and is the firm's biggest Life Sciences play since the acquisition of Pall for $13.8 billion in 2015.

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Emerging Tests: Medicare to Cover Next Gen-Sequencing Tests for Advanced Cancer, *from page 1*

Coverage of Non-Approved NGS Cancer Tests

The NCD covers certain NGS tests for certain cancer patients for use in limited situations. Let's go through the basic coverage requirements one by one.

1. Patient Must Have "Advanced Cancer"

Under the NCD, NGS tests are approved only for patients with "advanced cancer," i.e., cancer that is:

- Recurrent;
- Metastatic;
- Relapsed;
- Refractory;
- Stage III; or
- Stage IV.

2. Two Approved Uses

The NCD approves NGS testing for advanced cancer for only two kinds of uses:

- As a companion diagnostic "to identify patients with certain genetic mutations that may benefit from" FDA-approved treatments. "These tests can assist patients and their oncologists in making more informed treatment decisions," the NCD explains; and/or
- To determine a patient's eligibility for cancer clinical trials when the patient doesn't have a cancer mutation that matches to an NGS treatment.

3. Tests Must Qualify

The third condition relates to the NGS test itself. Under the NCD, tests currently or subsequently approved or cleared by the FDA as an *in vitro* cancer companion diagnostic are fully covered (provided, of course, that the other NCD conditions are met). Currently available tests with the requisite FDA approval include two assays from Foundation Medicine (whose stock price increased 3% after the NCD was published):

Test	Manufacturer
FoundationOne CDx (F1CDx)	Foundation Medicine
FoundationFocus CDxBRCA	Foundation Medicine
Praxis Extended RAS Panel	Illumina
Oncomine Dx Target Test	Thermo Fisher Scientific

The NCD also expands automatic coverage for FDA-approved tests for repeat testing when a patient has a new primary diagnosis. In addition, tests that have not been FDA cleared or approved may be covered if the local Medicare Administrative Contractor decides to cover them.

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Theranos & Its CEO Settle Stock Fraud Charges with SEC

Seven years ago, Theranos was a $9 billion dynamo seemingly on the precipice of blowing the blood testing market wide open. Today, the company and its CEO and founder, Elizabeth Holmes, are a beleaguered group surrounded by legal adversaries and struggling to survive. Recent months have seen the firm retrench and seek to settle its many legal fights. On March 14, Holmes and her company took a big step in that direction by settling with perhaps the most potent of its legal foes, the US Securities Exchange Commission.

The Settlement Deal

The SEC charged Theranos, Holmes and other corporate principals with securities fraud for allegedly making false claims about its prickless blood analyzing technology to raise over $700 million in investment capital. As it did with CMS and the Arizona State Attorney General, Theranos decided that settlement was the better part of valor and cut a deal with the SEC. Under the settlement, Holmes will pay a $500,000 penalty, disgorge the 18.9 million shares in Theranos stock allegedly acquired via the fraud and give up her voting control over the company. Holmes has also been barred for serving as an officer or director of a publicly traded company for 10 years.

According to the SEC, the defendants knowingly made false claims including predicting that the analyzer would generate over $100 million in 2014 revenues. Actual revenues came in just $99.9 million short of those projections. The SEC also charged the defendants with claiming that the product was used on the battlefield in Afghanistan and in medevac helicopters, neither of which was true.

Not included in the settlement is Theranos's former President Ramesh Balwani who will get the chance to prove his innocence in a US California District Court.

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

How about an Alexa for verbally querying genetic data? The Amazon Alexa-compatible "digital genetic assistant" from OptraGuru was among the more interesting new offerings of an otherwise slow period.

Here's a rundown of the key diagnostic product launches from late February to late March:

NEWLY LAUNCHED PRODUCTS & SERVICES

Company(ies)	Product(s)
Coriell Life Sciences	Solution for quantitative diagnosis and reporting of bacterial vaginosis
Sekisui Diagnostics	Silaris Influenza A&B test, 30-minute PCR-based point-of-care assay developed by Mesa Biotech
PierianDx	New clinical genomics services to complement firm's Clinical Genomics WorkSpace software product
Pacific Biosciences	New polymerase and version of its software for firm's Sequel instrument
BC Platforms	GeneVision software-as-a-service for precision medicine
Baylor Genetics	ClariFind, somatic tumor NGS test that analyzes alterations in 277 cancer genes for solid tumors and hematologic malignancies
Genomic Health	Oncotype DX AR-V7 Nucleus Detect Test, liquid biopsy assay for predicting treatment response in advanced prostate cancer patients
Tempus	Tempus xE, whole-exome sequencing panel that analyzes tumor DNA alongside a normal sample and a whole-RNA transcriptome
Optra Health	OptraGuru, an Amazon Alexa-compatible "digital genetic assistant" enabling consumers and healthcare professionals to verbally query genetic data

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Dx Earnings Report, *from page 1*

The other M&A deals during the period were more modest in scope and size. Agilent was the most active announcing a pair of acquisitions, including:

- An agreement to purchase Iowa-based capillary electrophoresis products maker Advanced Analytical Technologies for $250 million in cash; and
- SEC 10Q filing disclosure of its decision to exercise the $105 million option to acquire the remaining shares of Lasergen, the NGS technology firm in which it already owned a 48% stake as a result of an $80 million deal in March 2016.

The other big M&A story was the deal that did not come off—at least not the way it was supposed to, namely, the merger of Rosetta Genomics and Genoptix. After the former's shareholders rejected the $10 million merger deal, the sides announced they were on to Plan B, under which Genoptix would acquire Rosetta's PersonalizeDx business for $1 million in cash and then acquire the remainder of Rosetta for another $8 million. While the deal was approved by the boards of both companies, the shareholders have yet to weigh in. Meanwhile, Rosetta granted Genoptix worldwide distribution rights to all its testing products, including the flagship Reveal assay. The granted rights are exclusive within the US and non-exclusive in all other territories.

Strategic Alliances

Quest Diagnostics was among the most active in non-M&A strategic deal making, including a new collaboration with GenomicVision to develop biomarkers for SMA (spinal muscular atrophy) genetic detection and renewal as well as the renewal and expansion of an existing agreement with Vermillion for commercialization and test servicing of the latter's OVA1 ovarian cancer test.

The infiltration (for want of a better word) of consumer high-tech firms into the diagnostics realm continued with a pair of notable deals:

- WuXi NextCode's agreement to integrate its genomic data analysis products with Google Cloud platform and research tools to develop new interoperable sequencing products; and
- A three-way collaboration among Intel, Lenovo and Diaceutics to determine the feasibility of using artificial intelligence to group patients based on diagnostic testing data.

The other notable pattern from the period were the power deals pairing diagnostics giants in strategic collaboration. Examples include:

- A product integration between Royal Phillips and Hologic aimed at providing an end-to-end, seamless diagnostic experience for breast care clinicians and patients; and
- A 10-year agreement between Qiagen and Natera to develop cell-free DNA prenatal screening tests for use on Qiagen's GeneReader NGS system.

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Here's a summary of the key diagnostic deals from late February through late March:

MERGERS, ACQUISITIONS & ASSET SALES		
Acquiring Company	**Target(s)**	**Deal Summary**
Danaher	Integrated DNA Technologies	▪ Price: Estimated $1.9 billion ▪ Status: Expected to close mid-2018 ▪ Acquisition of privately held genomics consumables firm which will operate as standalone company within Danaher's Life Sciences segment after deal closes
Thermo Fisher Scientific	IntegenX	▪ Price: Undisclosed ▪ Status: Closed ▪ Acquisition of firm that develops rapid DNA testing for human identification in law enforcement and forensics
Agilent	Advanced Analytical Technologies	▪ Price: $250 million cash ▪ Status: Definitive agreement to acquire with no closing date announced ▪ Agilent acquires developer of capillary electrophoresis instruments, reagents and software for analyzing nucleic acids
Agilent	Lasergen	▪ Price: $105 million ▪ Status: Closed Feb. 23 announced in Agilent's most recent SEC 10Q filing ▪ Agilent exercises option to acquire remaining shares of NGS tech firm in which it had already acquired a 48% equity stake in 2016 ▪ Plan is to combine Agilent's engineering expertise with Lasergen's sequencing chemistry to build entire clinical sequencing workflow ▪ Newly merged firm to be called LaserGen
BioDuro	Molecular Response	▪ Price: Undisclosed ▪ Status: Closed ▪ Molecular Response, which provides cancer biobanking and tumor modeling services, to become subsidiary of BioDuro with former's CEO to become the latter's executive VP of translational sciences and strategy
PerkinElmer	RHS	▪ Price: $19.6 million ▪ Status: Expected to close June 11, 2018 ▪ Australia-based RHS sells whole-genome amplification and NGS platforms
Bruker	IRM	▪ Price: Undisclosed ▪ Status: Closed ▪ Acquisition of high-speed infrared imaging microscopy firm
Eurofins Scientific	NMDL-LCPL	▪ Price: Undisclosed ▪ Status: Closed ▪ Acquisition of Dutch molecular DX testing and pathology firm gives Paris-based Eurofins Scientific platform to grow its testing portfolio in Netherlands

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	**Partner 2**	**Deal Summary**
Laboratory Corporation of America	Interpace Diagnostics Group	▪ Objective: Expand LabCorp's cytology network ▪ Dynamic: Enable physicians to order both thyroid biopsy analysis and molecular testing from Interpace, as well as use LabCorp's Dianon Pathology for biopsy analysis ▪ Interpace to perform its molecular test in event of indeterminate results of tests or biopsy
Qiagen	Natera	▪ Objective: Develop cell-free DNA prenatal screening assays for use on Qiagen's GeneReader NGS system ▪ Dynamic: 10-year agreement under which Qiagen will pay Natera $40 million in up-front licensing fees and $10 million in milestone and ongoing royalty payments ▪ Each company to bear its own development costs for assays
Royal Phillips	Hologic	▪ Objective: Enable delivery of tailored, seamless breast care experience for women ▪ Dynamic: Combine Philips' imaging systems and services with Hologic's mammography technologies to offer a complete set of innovative diagnostic imaging systems, software and services
PerkinElmer	Nightingale Health	▪ Objective: Develop new precision medicine solutions ▪ Dynamic: Combine Nightingale's MRI biomarker assay for disease screening, diagnostics and treatment-efficacy assessment with PerkinElmer's sequencing services

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STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	**Partner 2**	**Deal Summary**
Quest Diagnostics	GenomicVision	▪ Objective: Develop new biomarkers to improve genetic detection of spinal muscular atrophy ▪ Dynamic: Expansion and extension of existing collaboration that began in 2011 ▪ Companies also agreed to develop tests for cancer and neurological disorders with Quest to provide testing services
Quest Diagnostics	Vermillion	▪ Objective: Amend current commercialization and services agreement for Vermillion's OVA1 ovarian cancer test ▪ Dynamic: In addition to extending deal one more year (to March 2019), Vermillion to pay Quest an annual fee of $150K for services of a full-time Quest project manager to handle issues related to OVA1 and Overa specimens sourced to Quest's testing lab
Quest Diagnostics	Rutgers University-New Brunswick	▪ Opening of the new Quest Diagnostics Sports Science Laboratory at the Rutgers Center for Health & Human Performance
Diaceutics	Lenovo + Intel	▪ Objective: Use artificial intelligence to determine if patients can be grouped based on diagnostic test information ▪ Dynamic: Use Lenovo ThinkStation P920 workstation powered by Intel Xeon Scalable processors to analyze Diaceutics' patient testing data database
WuXi NextCode	Google	▪ Objective: Develop new suite of interoperable sequencing products ▪ Integrate WuXi's genomic data analysis platforms with Google Cloud platform and genomics research tools ▪ First offering slated for May 2018
Fast Track Diagnostics	University of Liverpool	▪ Objective: Develop commercial blood test for diagnosing and treating meningitis ▪ Dynamic: UL to do the research and Fast Track, which was recently acquired by Siemens Healthineers, and UK's Medical Research Council to provide $2.2 million in funding ▪ Plan is to develop test within 3 years and link it to existing clinical trials in UK and Europe
Cofactor Genomics	National Cancer Institute (+ 3 other unnamed academic and pharma groups)	▪ Objective: Validate Cofactor Paragon RNA-based immune-profiling assay ▪ Dynamic: Material transfer agreement allowing researchers to use clinical specimens from NCI's clinical trials to understand immune profiles of patients with sarcoma, prostate cancer, lung cancer, breast cancer and bladder cancer ▪ Cofax to use study data to turn Cofactor Paragon into an off-the-shelf sequencing kit, with complementary cloud-based informatics
Quanterix	Destina Genomics	▪ Objective: Study use of Quanterix's Simoa technology for detecting microRNAs ▪ Dynamic: Phase 1: Develop assay to detect and quantify liver toxicity biomarker microRNA-122 to run on Simoa platform
Genetic Technologies	University of Melbourne	▪ Objective: Expand GT's BrevaGenplus breast cancer risk assessment test ▪ Dynamic: Test currently targets women 35 or older who haven't had breast cancer but have one or more risk factors ▪ Plan is to expand application of test to expand the test's use to women with extended family history of breast cancer
Foundation Medicine	Chugai Pharmaceutical (member of the Roche Group)	▪ Objective: Broaden patient access to Foundation's cancer genomic profiling services in Japan ▪ Dynamic: Chugai to be marketing authorization holder for FoundationOne CDx genomic solid tumor profiling assay in Japan if and when it gets regulatory approval in Japan ▪ Chugai to also lead commercial efforts for all of Foundation Medicine's cancer profiling assays in Japan ▪ Leverage Somalogic's SomaScan proteomic platform to measure large numbers of proteins in blood and other patient samples ▪ Latest step in Somalogic's larger strategy to develop SomaScan as clinical tool
Guardant Health	National Cancer Center Hospital East	▪ Objective: Support Japanese clinical study matching patients with advanced gastrointestinal cancer to novel therapies targeting specific gene alterations ▪ Dynamic: Guardant360 liquid biopsy assay to be used in study
Illumina	Chinese Medical Genetics Association	▪ Objective: Whole-genome sequencing for Chinese children with birth defects and rare undiagnosed diseases ▪ Dynamic: CMGA to draft guidelines on clinical application of whole-genome sequencing in pediatrics
PlumCare	Cordlife Group (Singapore)	▪ Objective: Offer genetic testing services in Asia ▪ Dynamic: Cordlife to launch PlumCare DNA Advisor test which identifies gene variants associated with increased risk of developing inherited conditions like breast and ovarian cancer under product's Genscreen brand in Asia

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STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	**Partner 2**	**Deal Summary**
Invitae	Kew	▪ Objective: Develop tumor genomic profiling capabilities for Invitae's NGS platform ▪ Dynamic: Invitae to fund efforts to integrate Kew's CancerPlex assay into its platform and workflow ▪ Invitae also gets access to Kew's bioinformatics software
Cancer Genetics	PierianDx	▪ Objective: Develop precision oncology testing platform ▪ Dynamic: Product integration combining Cancer Genetics' Focus:NGS tests for analyzing solid tumors and hematologic malignancies with PierianDx's Clinical Genomics WorkSpace NGS data management software
Exosome Diagnostics	Intezyne	▪ Objective: to design and validate an exosomal RNA assay for use in Intezyne's Phase 1/2 clinical trials of IT-139, a novel Cancer Resistance Pathway inhibitor ▪ Dynamic: Assay will use Exosome Diagnostics' Exolution isolation kit to stratify longitudinally monitor patients
OpGen	Beth Israel Deaconess Medical Center	▪ Objective: Verification study for OpGen's Acuitas AMR Gene Panel u5.47 Assay and Acuitas Lighthouse Knowledgebase ▪ Dynamic: Study among first to examine potential diagnostic and antibiotic decision-making improvements that may be possible using rapid molecular testing and bioinformatics
Bruker	Evosep	▪ Objective: Spectrometry and liquid chromatography codevelopment and comarketing ▪ Dynamic: Bolster integration of Evosep One LC system with Bruker's timsTOF Pro mass spec by using Bruker's Hystar LC-MS control software to control both systems
Vortex Biosciences	BioView	▪ Objective: Develop integrated workflow for identifying clinical biomarkers on circulating tumor cells ▪ Dynamic: Product integration combining Vortex Biosciences' VTX-1 Liquid Biopsy System with BioView's Duet imaging system and CTC analysis algorithm
BGI	South African Medical Research Council	▪ Established the Cape Town-African Genomics Centre
2bPrecise	Avera Health	▪ Objective: Develop platform to deliver results of Avera Heath's GeneFolio medication test to physicians ▪ Dynamic: 2bPrecise's its cloud-based platform for capture and dissemination of genomic information to be used to structure and deliver GeneFolio results to physicians within the Avera system
Genetic Technologies (Australia)	Omix Ventures	▪ Objective: Develop global genomic data management platform for cancer DX development ▪ Dynamic: Genetic to provide Omix's Project Shivom sample processing and other services through via its Victoria CLIA lab ▪ Genetic gets right to use Project Shivom' Global Genome ID data to develop new tests for predicting cancer, as well as data-monitoring and risk-assessment kits and services ▪ Genetic to become member of Project Shivom's lab and genetic counseling networks
3D Signatures	Quebec Heart and Lung Institute (IUCPQ)	▪ Objective: Study clinical use of 3D's TeloView software with DNA sequence analysis in lung cancer patients ▪ Dynamic: IUCPQ to do whole-exome sequencing on patients with non-small cell lung cancer and provide matching tissue samples from its tumor bank ▪ Study to be run by 3D at its Toronto-based lab in partnership with IUCPQ researcher
Pronto Diagnostics	FDNA	▪ Objective: Product integration ▪ Dynamic: Combine Pronto's genetic tests with FDNA's 'Face2Gene phenotyping applications
SeqOne	Gene42	▪ Objective: Develop solutions allowing for faster, more accurate diagnoses of rare conditions ▪ Dynamic: Study combining SeqOne's personalized medicine software with Gene42's genome analysis platform
BGN Technologies	Biosensorix (Singapore)	▪ Objective: Develop quantitative point-of-care diagnostics ▪ Dynamic: Envisioned technology is an electrochemical lateral flow immunosensor test to quantitatively diagnose disease-related biomarkers and pathogens ▪ New system to leverage PlexBio's multiplex πCode MicroDisc technology and initially focus on tests for sepsis and multidrug resistance
Edico Genome	InterSystems	▪ Objective: Enable clinicians to use Edico's DRAGEN Clinical Genomics Information System to order and view results of NGS tests ▪ Dynamic: Integrate DRAGEN with InterSystems' HealthConnect platform to
Planet Innovation	Preora Healthcare	▪ Objective: Develop cancer screening tests ▪ Dynamic: Tests to employ Preora's partial-wave spectroscopy cytology platform and sample-preparation technologies ▪ First test to screen for first-tier lung cancer screening with colorectal cancer, prostate cancer, and other solid-tumor malignancy tests to follow

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STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	**Partner 2**	**Deal Summary**
BGI	Ethiopian Biotechnology Institute	▪ Objective: Support genomics and biotech research ▪ Dynamic: Partners to share R&D information and establish research facilities and laboratory infrastructure
Mologic	Fraunhofer	▪ Objective: Develop rapid, point-of-care test for bacterial urinary tract infections and associated antibiotic susceptibility for use in primary care ▪ Dynamic: Other partners include Wideblue, Kelvin Nanotechnology, University of Strathclyde and Barclay Medical Practice
RPS Diagnostics	Atomo Diagnostics	▪ Objective: Develop FebriDx, point-of-care test to detect febrile acute respiratory infections and differentiate between viral and bacterial infection ▪ Dynamic: FebriDx to use Atomo Diagnostics' all-in-one rapid diagnostic test platform

DISTRIBUTION, SALES & MARKETING AGREEMENTS		
Property Owner	**Distributor**	**Deal Summary**
Akonni Biosystems	Righton	▪ Products: Akonni's TruTip sample preparation technology and TruDiagnosis its multiplexed diagnostics solution ▪ Territory: China ▪ Exclusive two-way licensing deal (see below for the other half) which also provides for Righton to support China launch of Akonni's TB diagnostics products
Righton	Akonni Biosystems	▪ Products: Righton's molecular DX product line ▪ Territory: Global (excluding China) ▪ Exclusive two-way licensing deal (see above for the other half)
Technopath Clinical Diagnostics (Ireland)	Beckman Coulter Diagnostics	▪ Products: Technopath's Multichem QC products, including quality control materials and IAMQC data management platform ▪ Territories: Over 100 countries
Rosetta Genomics	Genoptix	▪ Products: All Rosetta testing products including flagship Reveal assay ▪ Territory: Global ▪ Exclusive in US, non-exclusive in all other territories ▪ Deal part of salvage of recent aborted merger between the parties
Empire Genomics	Resnova	▪ Products: Empire's FISH tests and services ▪ Territory: Italy

LICENSES		
Licensor	**Licensee**	**Deal Summary**
Memorial Sloan Kettering Cancer Center	Personal Genome Diagnostics	▪ Property: TMB (Tumor mutation burden)-related intellectual property ▪ Personal Genome acquires exclusive right to use property develop and commercialize products and services that include assessment of TMB biomarker status

SUPPLY, SERVICE & TESTING AGREEMENTS		
Supplier/Servicer	**Client**	**Deal Summary**
MDxHealth	Fondazione Luigi Maria Monti - Istituto Dermopatico dell' Immacolata (IDI) research Hospital (Italy)	▪ MDx to provide its SelectMDx prostate cancer test to IDI patients as a service

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FDA Watch: 23andMe Continues to Spearhead Direct-to-Consumer Marketing of LDT Genetic Tests

On March 6, the FDA announced its first ever approval of a direct-to-consumer breast cancer gene test—23andMe's genetic health risk report for detecting BRCA1 and BRCA2 genetic mutations most commonly found in people of Ashkenazi Jewish descent. But in announcing the approval, the FDA also took pains to point out its "caveats." According to Donald St. Pierre, FDA acting director of the Office of In Vitro Diagnostics and Radiological Health:

- The test should not be used as a substitute for seeing your doctor for cancer screenings or counseling on genetic and lifestyle factors that can affect cancer risk;
- The test does not provide information on a person's overall risk of developing any type of cancer;
- Use of the test carries significant risks if individuals use the test results without consulting a physician or genetic counselor;
- Test results should not be used to make treatment decisions such as prophylactic removal of breasts or ovaries.

A Blood Test Breakthrough

Still, the approval continues the FDA's new liberal policies on DTC testing. Last April, the agency gave 23andMe the greenlight to engage in DTC marketing of its Personal Genome Service Genetic Health Risk (GHR) tests for 10 diseases or conditions. (See *NIR*, April 26, 2017 for the details.)

And in December, the FDA proposed new rules allowing for DTC marketing of genetic tests without premarket approval in limited situations. (See *NIR*, Dec. 11, 2017 for the details.)

Other New FDA Approvals

Meanwhile, here's a rundown of the other key new FDA approvals announced from late February through late March

NEW FDA APPROVALS

Manufacturer(s)	Product(s)
Longhorn Vaccines and Diagnostics	*De novo* clearance of PrimeStore Molecular Transport Medium for stabilizing microbial nucleic acids
AESKU.Group	510(k) clearance of AESKUSLIDES nDNA lupis diagnostic test for use with firm's Helios automated IFA system
Exalenz Bioscience	510(k) clearance of BreathID Hp point-of-care system and BreathID Hp Lab system for detecting *H. pylori* infection in adults extended to include detection of H. pylori infection in kids ages 3 to 17
Roche	510(k) clearance of Cobas m 511 hematology testing solution
Roche	510(k) clearance of Elecsys tumor-associated antigen immunological assay

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NEW FDA APPROVALS, *Cont'd.*

Manufacturer(s)	Product(s)
23andMe	Authorization for direct-to-consumer marketing of three BRCA1 and BRCA2 mutations commonly found in individuals of Ashkenazi Jewish descent
Oxford Immunotec	Approval of tests screening whole blood and plasma for a tick-borne disease known as babesiosis
DiaSorin	510(k) clearance of received clearance of Liaison BRAHMS PCT II Gen assay for quantitative determination of procalcitonin in human serum and lithium heparin plasma specimens
Quidel	510(k) clearance of Sofia Lyme Fluorescent Immunoassay for detecting human IgM and IgG antibodies to *Borrelia burgdorferi* in serum or plasma samples
Alfa Scientific Designs	510(k) clearance and CLIA waiver of ALFA's immunoassay fecal occult blood (iFOB) test with Driven FlowTechnology

During the period, the following FDA CLIA waivers were announced:

NEW FDA CLIA WAIVERS

Manufacturer(s)	Product(s)
Alfa Scientific Designs	ALFA's iFOB with Driven Flow Technology.

New CE Marks & Global Certifications

Notable European CE certifications:

NEW CE CERTIFICATIONS

Manufacturer(s)	Product(s)
Agendia	Approval of MammaPrint BluePrint, NGS kit for breast cancer recurrence risk testing and molecular subtyping
Saladax Biomedical	Approval of MyCare Total Risperidone Assay Kit measuring total risperidone in patient's blood
Saladax Biomedical	Approval of MyCare Paliperidone Assay Kit measuring total paliperidone in patient's blood
Qiagen	Approval of Artus T. vaginalis QS-RGQ kit
Becton Dickinson	Approval of PAXgene Blood ccfDNA tube

Other international clearances announced in the past month:

Manufacturer(s)	Product(s)	Product(s)
Thermo Fisher Scientific	Canada	Class III Medical Device System License to firm's BRAHMS business for four automated immunofluorescent assays used as prenatal screening aids
Siemens Healthineers	Canada	Approval to market its Symbia Intevo Bold SPECT/CT system

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By the Numbers: Spike in M.D. Practice Acquisitions Drives Up Costs of Hospital Care

Hospitals are gobbling up M.D. practices at a record rate. In addition to endangering the independent physician practice, this trend is driving up the costs of hospital care by adding ever higher numbers of physicians to hospital payrolls. Consider the following numbers, which come from a new research study:

- **5,000:** Number of M.D. practices acquired by hospitals from July 2015 to July 2016;
- **14,000:** Number of physicians who became hospital employees over the same period;
- **11:** Percentage by which acquisitions grew as compared to the same period from 2014-2015;
- **100:** Percentage by which hospital-owned physician practices has grown since 2012;
- **14,000:** Percentage by which acquisitions grew over the same period from 2014-2015;
- **63+:** Percentage by which the number of hospital-employed physicians increased from 2014-2016;
- **3.1 billion:** Increase in Medicare costs for four healthcare services as a result of higher hospital physician employment rates between 2012-2015, according to the study.

Source: *Updated Physician Practice Acquisition Study: National and Regional Changes in Physician Employment*, Physician Advocacy Institute and Avalere

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