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Upcoming Events

Lab Leadership Summits

**Lab Reimbursement
Summit 2019: Practical Strategies
for Maximizing Revenue and
Minimizing Claim Denials in 2019**

December 6, 2018, Las Vegas, NV
www.lableadershipsummits.com

Medicare Reimbursement: Part B Lab Payments in Final Year before PAMA

Part B payments for lab tests in 2017, the final year under the old reimbursement rules, totaled \$7.1 billion, up slightly from the \$6.8 billion Medicare paid in 2016 and little changed over the four-year baseline period leading into the new PAMA market-based pricing system, according to an OIG report.

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

The swirl of autumn leaves has brought a swirl of diagnostic deals. Here's a recap of the key activity from mid-September through the third week of October.

M&A and Asset Sales

Quest Diagnostics announced an agreement to sell its India medical diagnostics business to Bangalore-based specialized diagnostics company Strand Life Sciences. The acquisition is expected to be an important addition to Strand's 24 diagnostic labs across India, particularly as the company expands its work in oncology, genomics, and precision medicine. Terms of the deal, which is expected to close by the end of the first quarter of 2019, were not disclosed.

It's been a busy month for Quest, which has also acquired several companies. Details are provided in the chart below.

A deal not included in the chart but worth mentioning involves BioMérieux. The global in vitro diagnostic company announced it may eventually increase its previously announced minority stake in Suzhou Hybiome Biomedical Engineering, a Chinese firm that develops and manufactures a range of automated immunoassay analyzers that have been cleared by the China Food and Drug Administration.

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■ Medicare Reimbursement: Part B Lab Payments in Final Year before PAMA, from page 1

How Medicare Spent Its \$7.1 Billion for Lab Tests in 2017

Tests	Beneficiaries	Labs	Providers
433 million: total tests billed	28 million: beneficiaries that received at least one test	56,859: labs that received Medicare payments	655,771: providers that ordered lab tests
3.4: average number of tests received by beneficiaries per day	16: average number of tests per beneficiary	\$125,388: average payments per lab	466: average tests ordered per provider
17: average number of tests per day for top 1% of beneficiaries	86: average number of tests per beneficiary among top 1% of beneficiaries	\$1.1 billion: payments to top 3 labs	5,964: average tests ordered by top 1% of providers

Source: OIG, “[Medicare Payments for Clinical Diagnostic Laboratory Tests in 2017](#)”

* Note: For a comparison to 2016 data, see [NIR, Oct. 2017](#), page 1

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What Medicare Paid for Top 25 Lab Tests

While the top 25 most billed tests always generate the lion's share of Clinical Laboratory Fee Schedule (CLFS) payments, that trend was even more pronounced in 2017:

Year	Total	Percentage of All CLFS Payments
2017	\$4.5 billion	64%
2016	\$4.3 billion	63%
2015	\$4.1 billion	58%
2014	\$4.2 billion	59%



Investigative Journalist Wins Kellison Award

John Carreyrou, the Pulitzer prize-winning journalist

who exposed Theranos as a fraud, was presented with the Kellison & Company Distinguished Service Award at Lab Institute. Pictured here are Mark Ziebarth, Publisher and CEO at G2 Intelligence, which put on the 36th annual Lab Institute in Washington, DC Oct. 24-16 (left); award winner Carreyrou (center); and Kevin Ellison, founder of Kellison & Company, who presented the award (right). Carreyrou, a *Wall Street Journal* reporter, wrote a series of articles poking holes in the Theranos' claims of a breakthrough on testing with fingerprick samples of blood.

Other findings:

- ▶ 17 of the top 25 tests were in the top 25 for all four years of the baseline period;
- ▶ The top five tests accounted for \$2.2 billion, or 30% of all lab test payments in 2017;
- ▶ The rankings of the top five tests didn't change in four years;
- ▶ One percent of labs (272 out of 27,171 labs) received 55% of all Medicare payments for the top 25 lab tests in 2017.

How Medicare Spent Its \$7.1 Billion for Lab Tests in 2017

Rank	Test Description and Procedure Code	National Limitation Amount	Number of Tests (in millions)	2017 Medicare Payments (in millions)	Changes from 2016 Payments (in millions)
1	Blood test, thyroid-stimulating hormone (TSH) (84443)	\$23.05	21.5	\$484	+\$1.6
2	Blood test, comprehensive group of blood chemicals (80053)	\$14.49	41.6	\$473	+\$3.0
3	Complete blood cell count (red blood cells, white blood cells, platelets) and automated differential white blood cell count (85025)	\$10.66	41.5	\$432	-\$1.3
4	Blood test, lipids (cholesterol and triglycerides) (80061)	--	28.9	\$415	+\$4.4
5	Vitamin D-3 level (82306)	\$40.61	8.9	\$348	-\$1.9
6	Drug test(s), definitive, 22 or more drug class(es), including metabolite(s) if performed (G0483)	\$253.87	1.3	\$307	+65.3
7	Hemoglobin A1C level (83036)	\$13.32	19.7	\$257	+\$6.2
8	Testing for presence of drug (80307)	\$79.81	3.3	\$240	New code in 2017
9	Drug test(s), definitive, per day, 15-21 drug class(es), including metabolite(s) if performed (G0482)	\$204.34	0.8	\$162	+\$35.8
10	Blood test, basic group of blood chemicals (80048)	\$11.60	13.2	\$130	-\$3.7

Source: OIG, "[Medicare Payments for Clinical Diagnostic Laboratory Tests in 2017](#)" 

■ Diagnostic Deals, from page 1

A key trend appears to be driving M&A deals. Now that the [American Clinical Laboratory Association \(ACLA\) lawsuit against CMS](#) has been dismissed, there is greater clarity with regard to PAMA reimbursement rates; cuts to Medicare Part B prices will stand. In order to offset the reduction in revenues, diagnostic companies are looking to other sources, namely acquisitions. Of course, ACLA may appeal or there may be regulatory compromises. In the meantime, however, expect heavy M&A activity.

Strategic Alliances

Many new alliances were announced this past month, including expansion of a collaboration between LabCorp and Walgreens that was initially piloted at 17 Walgreens stores in 2017. Customers at an additional 600 Walgreens stores throughout the U.S. will now have access to LabCorp specimen collection and testing services.

LabCorp also has two other new alliances. Details are provided in the chart below. In addition to the alliances included the chart, there is another of note. It again has to do with Quest Diagnostics.

Quest has announced the formation of the Global Diagnostics Network (GDN), a partnership with other large labs across the globe aimed at sharing diagnostic innovation, information, and services in order to generate diagnostic insights and enhance global health care. GDN will initially focus on collaboration on companion diagnostics, and the creation of an emerging pathogen preparedness network to expedite infectious disease research and response. Network founding members are Al Borg Medical Laboratories, based in Saudi Arabia with labs across the Middle East and Africa; Dasa, based in Brazil; GC Labs, based in South Korea; KingMed Diagnostics, based in Hong Kong with labs across Southeast Asia; Primary Health Care, based in Australia; and SynLab, based in Germany with labs across Europe and on four continents. The GDN has a presence on every continent and collectively is present in countries with over half of the world's population.

Here's a summary of key diagnostic deals from mid-September through the third week in October:

MERGERS, ACQUISITIONS & ASSET SALES		
Acquiring Company	Target(s)	Deal Summary
Agilent Technologies	ACEA Biosciences	<ul style="list-style-type: none"> ■ Price: \$250 million cash ■ Status: Agreement to acquire with no closing date announced ■ Purchase of developer of xCELLigence real-time cell analysis instruments and NovoCyte and NovoCyte Quanteon high-performance benchtop flow cytometry systems most recent in string of 2018 acquisitions for Agilent
Quest Diagnostics	Oxford Immunotec Global	<ul style="list-style-type: none"> ■ Price: \$170 million cash ■ Status: Definitive agreement with no closing date announced ■ Acquisition of Oxford Immunotec's US lab business including T-Spot.TB tuberculosis and Accutix tick-borne disease testing services ■ Oxford Immunotec to sell T-Spot.TB test kits and accessories to Quest under long-term supply agreement ■ Sides also expect to enter strategic agreement to grow T-Spot.TB testing in US

MERGERS, ACQUISITIONS & ASSET SALES		
Acquiring Company	Target(s)	Deal Summary
Quest Diagnostics	ReproSource	<ul style="list-style-type: none"> Price: Undisclosed Status: Closed Quest to add Mass.-based firm's fertility diagnostics services to its women's health and reproductive line
Quest Diagnostics	Hurley Medical Center	<ul style="list-style-type: none"> Price: Undisclosed Status: Closed Quest acquires unspecified assets of Hurley's outreach lab services operation
Summit Health (Quest Diagnostics wellness sub)	Hooper Holmes, dba, Provant Health	<ul style="list-style-type: none"> Price: \$27 million Status: Closed Acquired company had filed for Chapter 11 after 2017 merger of Hooper Holmes and Provant Health left combined company with a working capital shortfall and over-leveraged balance sheet
Quest Diagnostics	PhenoPath	<ul style="list-style-type: none"> Price: Undisclosed Status: Closed PhenoPath's Anatomic Pathology, molecular oncology and other services to operate as part of Quest's AmeriPath business
Strand Life Sciences	Quest Diagnostics	<ul style="list-style-type: none"> Price: Undisclosed Status: To close in Q1 2019 Bangalore-based specialty DX firm to acquire Quest's medical diagnostics business in India
Exact Sciences	Biomatrix	<ul style="list-style-type: none"> Price: Undisclosed Status: Closed Producer of sample preservation technology, including blood and saliva sample collection tubes to operate as wholly owned subsidiary of Exact
Precision for Medicine	ApoCell	<ul style="list-style-type: none"> Price: Undisclosed Status: Closed Precision acquires biomarker identification and analysis firm
Predictive Technology Group	Taueret Laboratories	<ul style="list-style-type: none"> Price: Undisclosed Status: Closed Predictive acquires DNA and ancestry assets including 1,000 degenerative disc disease-related DNA samples, related family and clinical records, relevant clinical records and 800 ancestry matched control samples
LGC	Berry and Associates	<ul style="list-style-type: none"> Price: Undisclosed Status: Closed Acquisition of Berry's oligo reagents bolsters LGC's nucleic acid chemistry product line
Brooks Automation	GeneWiz	<ul style="list-style-type: none"> Price: Undisclosed Status: Expected to close by end of 2018 NJ-based GeneWiz provides genomic services, including Sanger sequencing, gene synthesis, cloning and mutagenesis, oligo synthesis and NGS

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	Partner 2	Deal Summary
LabCorp	Walgreens	<ul style="list-style-type: none"> Objective: Offer LabCorp testing services to Walgreens customers at store sites Dynamic: Expand current 4-year collaboration to 600 new Walgreens stores in addition to existing 17 LabCorp at Walgreens locations already open in Florida, Colorado, North Carolina and Deerfield, Illinois Co-branded patient service centers located near pharmacy area inside Walgreens stores where specimens are collected and sent to LabCorp's labs for testing

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	Partner 2	Deal Summary
Covance (part of LabCorp)	Definiens	<ul style="list-style-type: none"> Objective: Accelerate development of biomarkers, oncology drugs and companion diagnostics Dynamic: Combine Definiens uses machine learning and deep learning-based technology for profiling tumor microenvironments with Covance's biomarker identification and companion diagnostics development expertise
LabCorp	Baptist Health (BH)	<ul style="list-style-type: none"> Objective: Provide technical services and enhanced data analytics to BH's eight hospital-based labs Dynamic: Expansion of existing reference lab services relationship under which LabCorp will help create core lab at BH Louisville BH to own core lab and keep ownership of the eight hospital labs
DiaSorin Inc.	Meridian Bioscience	<ul style="list-style-type: none"> Objective: Sell DiaSorin's <i>H pylori</i> stool antigen test for use on Meridian Bio's Liaison platform Dynamic: Test to be sold under Meridian name worldwide with focus on US market Meridian Bio to receive royalties on US and UK sales
Myriad Genetics	Pfizer	<ul style="list-style-type: none"> Objective: Promote use of Myriad's BRACAnalysis CDx test for identifying patients suitable for treatment with Pfizer's talazoparib Dynamic: Commercialization plan under existing companion diagnostic agreement, in which Myriad is seeking FDA approval for its BRACAnalysis CDx® as a companion diagnostic with talazoparib, Pfizer's investigational PARP inhibitor
Celmatix	Teva Pharmaceutical (via Oncotest-Teva subsidiary)	<ul style="list-style-type: none"> Objective: Make Celmatix's Fertilome genetic test for reproductive health and fertility available in Israel Dynamic: First international expansion of Fertilome test
ArcherDx	Merck KGaA	<ul style="list-style-type: none"> Objective: Commercialize NGS-based companion test for unnamed Merck drug candidate Dynamic: Archer to use its ArcherDx platform to develop and seek regulatory approval for CDx to identify patients potentially benefiting from Merck drug
Atomo Diagnostics	Mylan Pharmaceuticals	<ul style="list-style-type: none"> Objective: Commercialize Atomo's HIV self-tests, already CE marked in Europe, in low- and middle-income nations Dynamic: Mylan gets exclusive rights to commercialize the tests in over countries in Africa, Asia, Middle East, Commonwealth of Independent States and Latin America
Roche Diagnostics	Genialis	<ul style="list-style-type: none"> Objective: Develop streamlined NGS workflow for drug discovery Dynamic: Integrates Roche's KAPA RNA HyperPrep Kits with Genialis' software platform
Foundation Medicine	Novartis	<ul style="list-style-type: none"> Objective: Develop companion diagnostic tests for Novartis targeted oncology and immuno-oncology drugs Dynamic: Use FoundationOne CDx genetic profiling assay to develop, gain regulatory approval and commercialize CDx includes development, regulatory support and commercialization of companion diagnostic tests Agreement allows for global expansion in non-US markets including Japan
BGI Americas	Gencove	<ul style="list-style-type: none"> Objective: Merge respective technologies to create single low-pass sequencing service signatures for therapeutic response Dynamic: Combine join BGI's DNBseq NGS technology with Gencove's ImputeSeq low-pass sequencing analysis pipeline
GeneWiz	Nashville Biosciences	<ul style="list-style-type: none"> Objective: Develop extensive research support product Dynamic: Combine Nashville Bio's BioVU biobank with GeneWiz's NGS services
Celcuity	Puma Biotechnology	<ul style="list-style-type: none"> Objective: Use Celcuity's CELx HER2 Signaling Function test to evaluate efficacy and safety of Puma Bio's Nerlynx (neratinib) and chemotherapy on patients with early-stage triple-negative breast cancer Dynamic: Phase II clinical trial sponsored by West Cancer Center
Diagnomics	Translational Software	<ul style="list-style-type: none"> Objective: Offer comprehensive and customized pharmacogenetic test reports Dynamic: Analysis to be performed on Illumina's Global Screening Array with report evaluating patient's likely drug response, metabolism, and treatment efficacy generated using Translational Software's platform
Bio-Techne	Micropoint Bioscience	<ul style="list-style-type: none"> Objective: Develop point-of-care diagnostic tools for Chinese market Dynamic: Integrate Bio-Techne's ProteinSimple Ella microfluidic multianalyte immunoassay with Micropoint's microfluidic chip for point-of-care testing in China

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	Partner 2	Deal Summary
Origimed	Members include nearly 40 local hospitals led by Beijing Xisike Clinical Oncology Research Foundation and East Clinical Center of Ontology	<ul style="list-style-type: none"> Objective: New initiative to create cancer genetics database specific to Chinese population Dynamic: Project, called Special Chinese Big Data Platform for Cancer Genomics Informatics, to gather data on roughly 5,000 Chinese patients to help identify genetic drivers of cancer and factors for metastasis, disease relapse, drug efficacy and toxicity
Fulgent Genetics	StemCyte	<ul style="list-style-type: none"> Objective: StemCyte to offer Fulgent's genetic testing services Dynamic: Strategic partnership to include Fulgent's Beacon Expanded Carrier Screening and Newborn Genetic Analysis
Genexosome Technologies (US subsidiary of Avalon GloboCare)	Weill Cornell Medicine	<ul style="list-style-type: none"> Objective: Standardize processing of cGMP-grade exosomes for clinical studies using Genexosome's exosome isolation platform from human endothelial cells Dynamic: Codevelopment program also seeks to identify and isolate tissue-specific exosomes for liquid biopsy and clinical use Includes material transfer agreement letting Weill Cornell use Genexosome's isolation system
Cancer Genetics	Cellaria	<ul style="list-style-type: none"> Objective: Develop precision medicine tools and platform technologies to support oncology therapeutics development Dynamic: Cancer Genetics' Genomics Center of Excellence to characterize Cellaria's biopharma products line and use its biomarker and genomics testing capabilities to study patient diversity focusing on solid tumors in primary and metastatic disease
Geneseq Biosciences	Australian Clinical Labs (ACL)	<ul style="list-style-type: none"> Objective: Commercialize Melaseq, Geneseq's blood-based melanoma detection test Dynamic: Geneseq gains access to agreement gives us access to ACL's clinical and biospecimen network
Genomics England	Iqvia	<ul style="list-style-type: none"> Objective: Develop platform for bringing together clinical and genomic data in support of evidence-based precision medicine and drug discovery Dynamic: Iqvia, formerly known as Quintiles IMS, to offer its E360 analytics technology to authorized users of Genomics England's database of de-identified genomic and phenotypic records
Centogene	Denali Therapeutics	<ul style="list-style-type: none"> Objective: Conduct targeted global patient identification and recruitment campaign for Centogene's Parkinson's disease LRRK2 inhibitor program Dynamic: Centogene to use its CentoCard dried blood spot collection kit to collect samples for identifying Parkinson's patients with mutations in LRRK2 gene
IDbyDNA	The Rady Children's Institute for Genomic Medicine	<ul style="list-style-type: none"> Objective: Study diagnostic capabilities of sequencing technologies in pediatric central nervous system infections Dynamic: Multi-site trial to evaluate clinical utility of IDbyDNA's NGS system for directly identifying pathogens in pediatric patients with suspected CNS infections
Evonetix	LioniX International	<ul style="list-style-type: none"> Objective: Create prototype microelectromechanical systems (MEMs) for DNA synthesis Dynamic: LioniX to use semiconductor microfabrication techniques and materials to manufacture the silicon array to be used by Evonetix to synthesize <i>de novo</i> DNA
BGI	Maxwell Plus	<ul style="list-style-type: none"> Objective: Develop model for predicting risks of prostate cancer patients' developing advanced or metastatic disease Dynamic: Use Maxwell's artificial intelligence technology to analyze data from patient samples sequenced on BGI's MGISEQ-2000 instrument with sequencing to be done at BGI's Australia lab
Protagen	National Center for Tumor Diseases + NEC Laboratories Europe	<ul style="list-style-type: none"> Objective: Improve approaches for in silico prediction of immunotherapy response in malignant melanoma patients Dynamic: Use machine learning to develop biomarker models for immunotherapy endpoints, including adverse effects, clinical response and survival
DCN Dx	E25Bio (MIT spinout)	<ul style="list-style-type: none"> Objective: Develop single infectious disease testing device for detecting dengue, Chikungunya and Zika viruses Dynamic: Leverage E25Bio rapid, low-cost, highly-specific and sensitive fingerstick blood test technology developed at MIT lab for onsite detection and global epidemiological analysis
Cytox	Australian Imaging, Biomarker, and Life-style Flagship Study of Ageing (AIBL)	<ul style="list-style-type: none"> Objective: Test new algorithms for identifying individuals at risk for developing Alzheimer's disease Dynamic: Expansion of existing alliance leveraging Cytox's variaTECT SNP array and SNPfitR interpretive software to assess genetic risk for accelerated development of Alzheimer's among pre-symptomatic and mild cognitively impaired people using its currently available technologies on biobanked samples provided by AIBL

DISTRIBUTION, SALES & MARKETING AGREEMENTS

Property Owner	Distributor	Deal Summary
Cancer Genetics (CGI)	GeneCast Biotechnology	<ul style="list-style-type: none"> Products: CGI's microarray gene expression Tissue of Origin test Territory: China Exclusive
Curetis	Beijing Clear Biotech	<ul style="list-style-type: none"> Products: Curetis Unyvero A50 platform and assay Territory: China Expansion of exclusive distribution deal from five to eight years following first Chinese regulatory approval
CopyCount-CNV	Fluidigm	<ul style="list-style-type: none"> Product: CopyCount-CNV's DNA Software for use with Fluidigm's Biomark HD system Territory: Not specified Non-exclusive

LICENSES

Licensor	Licensee	Deal Summary
Arcis Biotechnology	Teleflex	<ul style="list-style-type: none"> Property: Arcis' nucleic acid sample preparation chemistry Technology access agreement allowing Teleflex to use technology to develop a rapid diagnostic assay using RNA detection
Avacta	New England Biolabs (NEB)	<ul style="list-style-type: none"> Property: Avacta's affimer technology NEB gets right to commercialize assay using Actava's affimers that it's developing
BioAffinity Technologies	Precision Pathology Services	<ul style="list-style-type: none"> Property: BioAffinity's CyPath Lung laboratory-developed test for early-stage lung cancer diagnosis Deal provides for continued development and commercial sale of assay which Precision Pathology will market
ERS Genomics	GenAhead Bio	<ul style="list-style-type: none"> Property: ERS' CRISPR-Cas9 genome editing patents GenAhead to offer CRISPR-Cas9 services to pharmaceutical companies and researchers to produce cells with precise genetic modifications utilizing high knock-in efficiency in mammalian cell lines Non-exclusive
ERS Genomics	Axcelead Drug Discovery Partners	<ul style="list-style-type: none"> Property: ERS' CRISPR-Cas9 genome editing patents Axcelead said it plans to use CRISPR-Cas9 property to enhance its drug discovery service offerings Non-exclusive
Thermo Fisher Scientific	Siemens Healthineers	<ul style="list-style-type: none"> Property: Thermo Fisher's BRAHMS PCT procalcitonin biomarker assay Sixth licensing agreement of assay
University of North Carolina at Chapel Hill	GeneCentric	<ul style="list-style-type: none"> Property: UNC's NGS-based PuriST pancreatic cancer subtyping technology Exclusive

SUPPLY, SERVICE & TESTING AGREEMENTS

Supplier/Service	Client	Deal Summary
Quest Diagnostics	Regional Medical Center Health System	<ul style="list-style-type: none"> Quest to provide lab reference testing and supply chain support to regional health care provider for 5-county service area in northeast Alabama
Expedeon	Reszon Diagnostics International (Malaysia)	<ul style="list-style-type: none"> 3-year agreement to supply Reszon colloidal gold
Agilent Technologies	Cancer Genetics	<ul style="list-style-type: none"> Non-exclusive supply agreement under which Agilent will produce and provide CGI probe reagents for its FISH-based HPV-Associated Cancer Test assessing genomic changes associated with cervical cancers to identify patients at high risk for disease progression

FDA Watch: Changes to CBER Email Policy May Affect Your Lab

Heads up to any lab that's subject to oversight by the CBER, i.e., the FDA agency responsible for regulating biological products for human use. The agency changed its email communications policy on Oct. 1 and from now on will send emails containing regulatory information only to recipients with secure email accounts. If your email account isn't up to CBER standards, you're likely to miss out on crucial communications.

Which Labs Are at Risk

Under the new policy, CBER requires an email address with a unique domain name to consider a recipient a "secure email partner." As a result, the CBER will not send emails containing regulatory information to your lab if it uses as its business communications email:

- ▶ An ISP email address such as Comcast.net or Verizon.net;
- ▶ Gmail or Yahoo for email; or
- ▶ A personal email account like Gmail.

Creating a New Account

Bottom line: If your email address doesn't include a unique domain name, and you wish to continue to receive regulatory information from CBER via email, you'll have to create a new account. This isn't as difficult as it may sound. Gmail for Business, Office 365, and others offer secure hosted solutions. Outlook 2016 running on Windows 10 or Mac Sierra is another option.

Security Settings

However, simply creating an account with a unique domain isn't enough. Security settings must meet FDA secure email guidelines. These guidelines can be found here (<https://www.fda.gov/downloads/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/UCM622332.pdf>) If you're not tech savvy or feel overwhelmed by the instructions, you can contact the FDA for assistance by using one of the email addresses provided.

Other Communication

It's important to note that while a secure email address is required to receive and send regulatory communication from and to CBER, general communication that isn't regulatory in nature, e.g., driving directions to the FDA campus, may be sent by unsecure email. For technophobes who wish to continue to receive regulatory information, there's another option: CBER will send hard copies of this communication via the U.S. Postal Service upon request.

New FDA Approvals

Here's a look at some of the key FDA approvals announced at the end of September through the third week of October:

NEW FDA APPROVALS

Manufacturer(s)	Product(s)
Adaptive Biotechnologies	De novo designation for clonoSEQ assay to detect and monitor minimal residual disease in patients with multiple myeloma and B-cell acute lymphoblastic leukemia
Myriad Genetics	Approval of BRACAnalysis CDx for identifying HER2-negative, metastatic breast cancer patients with inherited BRCA1 and BRCA2 genetic mutations that may benefit from treatment with Pfizer's Talzena (talazoparib)

Manufacturer(s)	Product(s)
Progenika Biopharma	Approval of ID Core XT molecular assay for blood donor and patient non-ABO red blood cell types for determining blood compatibility for blood transfusions
PerkinElmer	Approval of NeoBase 2 Non-Derivatized MSMS kit for testing newborns for metabolic disorders with single dried blood spot
Applied BioCode	510(k) clearance for BioCode Gastrointestinal Pathogen Panel (GPP) with BioCode MDx-3000 molecular system
Qiagen	Approval of expanded use of Therascreen EGFR RGQ PCR Kit as companion diagnostic for Pfizer's Vizimpro (dacomitinib) for first-line treatment of patients with non-small cell lung cancer with EGFR exon 19 deletions or exon 21 L858R mutation
Premier Biotech	510(k) clearance for oxycodone assay for use on its OralTox oral fluid-based drugs of abuse device
Premier Biotech	510(k) clearance for methadone assay for use on its OralTox oral fluid-based drugs of abuse device
Abbott	Clearance for assay measuring magnesium in human serum, plasma or urine run on Abbott's Architect c8000 clinical chemistry system
Siemens Healthineers	Clearance for Innovance Free PS Ag assay for detecting free protein S antigen in human plasma collected from venous blood samples and running on Sysmex CS-5100 analyzer
Becton Dickinson	Clearance for BD Phoenix Automated Microbiology System for rapid identification and determination of antimicrobial susceptibility of gram-negative Enterobacteriaceae and non-Enterobacteriaceae bacteria
Becton Dickinson	Clearance for BD Phoenix CPO Detect confirmatory test to phenotypically detect carbapenemase-production in Enterobacteriaceae, Pseudomonas aeruginosa and Acinetobacter baumannii on gram-negative ID/AST or AST-only Phoenix panels
Roche	Clearance for Elecsys FT4 III Assay for measurement of free thyroxine used to diagnose and treat thyroid disease
Skyla	Clearance for Hi Hemoglobin A1c System (consisting of Hi Analyzer and Hi Hemoglobin A1c Reagent Kit) for measuring percent concentration of glycated hemoglobin in venous and finger-stick capillary whole blood
Princeton BioMeditech	Clearance for BioSign Flu A+B test to detect influenza type A- and B-nucleoprotein antigens directly from nasal swab, nasopharyngeal swab and nasopharyngeal aspirate specimens

New CE Marks & Global Certifications

Notable European CE certifications:

NEW CE CERTIFICATIONS IN EUROPE

Manufacturer(s)	Product(s)
Co-Diagnostics	CE-IVD marking for Logix Smart Zika screening test
DiaSorin	CE marking for Simplexa Group B Strep Direct molecular assay for use on firm's Liaison MDx instrument
DiaSorin	CE marking for its Simplexa VZV Direct Assay for detection of varicella-zoster virus that causes chickenpox and shingles from cerebrospinal fluid
Thermo Fisher Scientific	CE-IVD marking for Oncomine Dx Target Test NGS-based assay detecting cancer-driver gene variants
Becton Dickinson	CE-IVD marking for BD Max MDR-TB panel to detect tuberculosis-causing bacteria and mutations associated with resistance to isoniazid and rifampicin
Bioneer	CE-IVD marking for HIV-1 kit for quantifying RNA in blood samples run on firm's ExiStation system
Abbott	CE marking for announced today that High Sensitive Troponin-I blood test

Other international clearances announced in the past month:

Manufacturer(s)	Product(s)	Product(s)
AmoyDx	South Korea	Ministry of Food and Drug Safety approval for ROS1 fusion assay as companion diagnostic for Pfizer's non-small cell lung cancer (NSCLC) drug Xalkori (crizotinib)
Invivoscribe	Japan	Pharmaceuticals and Medical Devices Agency approval for LeukoStrat CDx FLT3 Mutation Assay companion diagnostic

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

The awakening from a sleepy summer that began in September picked up in intensity in October. Here's a rundown of the key new launches during the period.

NEWLY LAUNCHED PRODUCTS & SERVICES

Company(ies)	Product(s)
Roche	Avenio Tumor Tissue Targeted Kit NGS tumor analysis kit covering 17 genes to identify guideline-related biomarkers
Roche	Avenio Tumor Tissue Expanded Kit gene assay with both guideline-related and emerging biomarkers tumor analysis
Roche	Avenio Tumor Tissue Surveillance Kit NGS tumor analysis kit covering 197 genes for establishing a baseline for variants in longitudinal tumor burden monitoring
Roche	Global launch of Foundation Medicine's FoundationOne Liquid liquid biopsy test for solid tumors
Roche	Navify Clinical Trial Match to help oncologists access clinical trial information and publications available on Navify Tumor Board platform
Roche	Navify Publication Search to help oncologists access clinical trial information and publications available on Navify Tumor Board platform
Almac Diagnostic Services	claraT, software-driven tool for classifying biologically relevant gene expression signatures in comprehensive report
Ubiquitome	Liberty16 quantitative PCR system for personal and mobile DNA quantitation and testing
CeGaT	Analysis of tumor mutational burden (TMB) now being offered as standalone diagnostic
Genoox + Bionano Genomics	Genoox Integrated Platform for identifying structural variants
Sophia Genetics	Alamut Genovagome browser for variant exploration
DNAexus	DNAexus Apollo platform for clinico-genomic data science exploration, analysis and discovery
Empirical Bioscience	EB Pure Total RNA kit and EB Pure DNase 1 Digestion kit for purifying RNA from cells or soft tissue
Pacific Biosciences	Updates to Sequel sequencing system, including software version 6.0, reagents version 3.0 and SMRT cells 1M v3
Cellecta	CloneTracker XP Expressed Lentiviral Barcode Library product line
Cellecta	CloneTracker XP Barcoded CRISPR Library product line
Paragon Genomics	Research-use-only CleanPlex UMI Lung Cancer Panel
Paragon Genomics	has launched ParagonDesigner web-based tool enabling rapid design of CleanPlex Custom NGS Panels
Oxford Nanopore Technologies	New version of the flow cell for MinIon and GridIon sequencers that include the 'Rev D' ASIC

Continued on page 12

NEWLY LAUNCHED PRODUCTS & SERVICES, *Cont'd.*

Company(ies)	Product(s)
Oxford Nanopore Technologies	MiniIT, a compute module for use with MinIon sequencer
L7 Informatics (formerly Lab7 Systems)	Enterprise Science Platform version 2.0
Stratify Genomics	Prompt, new lab-developed test tracking men's genetic predisposition to prostate cancer
Precipio	HemeScreen test for mutations in hematologic cancers
Seq2Know	Now offering celiac disease testing
MNG Laboratories	MNG Xpress Exome diagnostic exome sequencing test identifying mutations in Mendelian disorders
Horizon Discovery	Myeloid DNA Reference Standard large cell-line derived myeloid cancer reference standard
Sysmex Inostics (subsidiary of Sysmex)	OncoBeam EGFR Kit V2 for research-use only in Europe and Asia
Mawi DNA Technologies	iSWAB-Cells platform for collecting and stabilizing intact cells for up to 4 weeks at room temperature
Konica Minolta	Konica Minolta Precision Medicine Japan to market high-end precision medicine tools and diagnostics in Japan



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