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LABORATORY INDUSTRY REPORT™

A DIVISION OF PLAIN LANGUAGE MEDIA

Vol. 20, Iss. 1
January 2020

HIGHLIGHTS

Diagnostic Deals: Illumina/PacBio Merger Derails & Qiagen Takes Itself Out of Play

As 2019 came to a close, the biggest story in DX deal making was the pair of anticipated M&A deals that suddenly seem unlikely to happen. As a result, two major genetic testing companies will apparently continue as stand-alones in the coming year, one because it wants to and the other because it has to.

FTC Foils Illumina-PacBio Merger

Announced at the end of 2018, the would-be $1.2 billion merger of Illumina and Pacific Biosciences has apparently

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Genetic Testing: New Medicare Early NGS Cancer Test Coverage Policy Is Less than Meets the Eye

For Myriad Genetics, Foundation Medicine and other manufacturers of next-generation sequencing (NGS)-based test panels for early-stage cancer risk assessment, the recent announcement of CMS' decision to provide limited Medicare coverage for germline breast and ovarian cancer looks like positive news. But while a lot better than the previous version, the proposed National Coverage Determination (NCD) is much less than even the half a loaf it looks like.

The NGS Testing Controversy

While the benefits of using NGS testing of BRCA1/2 genes to direct treatment of poly ADP ribose polymerase (PARP) inhibitors in advanced breast and ovarian cancer patients is well documented, the clinical utility of germline testing of early-stage patients for purposes of determining the need

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Diagnostic Deals, *from page 1*

foundered on the rocks of regulatory opposition. The genetic giants are facing strict antitrust scrutiny on both sides of the Atlantic. In the UK, the Competition and Markets Authority (CMA) review that was expected to take a couple of months has now expanded and dragged on until Feb. 5, 2020 at the earliest. On Dec. 17, the prospects of closing became even grimmer with word that the US Federal Trade Commission was taking action to block the deal claiming that Illumina is trying to maintain a monopoly in the US market for next-generation DNA sequencing systems by "extinguishing PacBio as a nascent competitive threat."

But Illumina isn't giving up, expressing "strong disagreement" with the FTC decision and vowing to continue to work through the regulatory approval process. Illumina's long-term future looks bright either way. Should the deal collapse, the real loser would be PacBio, which has been relying on cash infusions from Illumina to stay afloat. Even so, the promising beginning to the Sequel II launch could enable PacBio to turn things around and remain viable as a stand-alone company.

Qiagen to Remain a Stand-Alone

The other major genetic testing company that appeared in play was Qiagen. The one-two punch of disappointing third quarter earnings and loss of long-time CEO Peer Schatz, accompanied by a strategic pivot to team with long-time rival Illumina on NGS kits, seemed to mark turning points that compelled Qiagen to at least listen to acquisition offers, including from Thermo Fisher Scientific. Takeover rumors spread and drove up share prices with buyers anticipating major acquisition premiums.

But on Dec. 26, Qiagen put all the speculation to rest by announcing that it had decided to reject all the offers and remain a stand-alone company. The announcement also took the air out of the stock rally with Qiagen shares falling 21% in a single day.

Roche Pulls Plug on Syapse Collaboration

One of the key developments on the alliance making front was Roche's decision to terminate its partnership with software developer Syapse. Under the collaboration, which was announced in January 2018, Roche was going to finance the development of new precision medicine cancer technologies based on the Syapse platform, including a "learning health system" to provide physicians with continually updated evidence at the point of care. But less than two years in, Roche has decided to pull out without giving specific reasons. The deal won't affect Syapse's other current pharma partnerships with Pfizer and Amgen.

Here's a summary of key diagnostic deals announced from the third week of November through the end of 2019:

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Laboratory Industry Report (ISSN 1060-5118) is published by G2 Intelligence, Plain Language Media, LLLP, 15 Shaw Street, New London, CT, 06320.
Phone: 888-729-2315
Fax: 855-649-1623
Web site: www.G2Intelligence.com.

MERGERS, ACQUISITIONS & ASSET SALES		
Acquiring Company	Target(s)	Deal Summary
Illumina	Pacific Biosciences	• Price: $1.2 billion cash ($8 per share, representing 71% premium over market for 30 days ending Oct. 31, 2018) • Status: Closing delayed to spring 2020 at earliest due to antitrust concerns in US + UK • PacBio long-read sequencing technology complements Illumina short-read sequencing platforms and enables it to provide integrated workflows and innovations that leverage both technologies
Clayton, Dubilier & Rice investment funds	Cynosure (owned by Hologic)	• Price: $205 million cash (of which Hologic will net $138 million) • Status: Expected to close before end of 2019 pending regulatory approval • Hologic sells off medical aesthetics business it acquired for $1.6 billion in 2017 after $732 million value write down • Sale enables Hologic to concentrate breast health and molecular diagnostics core businesses
Tempus	Akesogen	• Price: Undisclosed • Status: Closed • Acquisition of genomics and clinical trial precision medicine services provider helps Tempus expand into disease areas outside of cancer
Oncology Pharma	Diagnomics	• Price: Undisclosed • Status: Letter of intent signed with no closing date announced • Oncology Pharma to acquire at least 50% of molecular genomic firm Diagnomics, including latter's stake in Eone-Diagnomics Genome Center
PerkinElmer	Shangdong Meizheng Bio-Tech	• Price: $152 million + additional contingent consideration of up to $26 million • Status: Closed • Acquisition of bioscience company offering products for food safety + environmental monitoring
Tulip Diagnostics (owned by PerkinElmer)	Biosense Technologies	• Price: Undisclosed • Status: Closed • Acquisition of Mumbai, India-based developer of point-of-care, in vitro diagnostic solutions
Unilabs	Saltro	• Price: Undisclosed • Status: Expected to close Jan. 1, 2020 pending regulatory approval • Acquisition expands Swiss lab's presence in Netherlands market
Quest Diagnostics	Boston Clinical Laboratories (BCL)	• Price: Undisclosed • Status: Closed • Acquisition of BCL's clinical laboratory services business driven by PAMA Medicare price cuts
Canopy Biosciences	Core Diagnostics	• Price: Undisclosed • Status: Closed • Canopy acquires Core's CLIA facility, from which it will provide its multi-omic immune profiling services

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Diagnostic Deals, *from page 3*

MERGERS, ACQUISITIONS & ASSET SALES		
Acquiring Company	Target(s)	Deal Summary
Phenomics Health	Precera Bioscience	• Price: Undisclosed • Status: Closed • Phenomics acquires Precera's PrecisMed technology for analyzing blood from a finger prick to detect, measure + assess over 200 medications in bloodstream
Medix Biochemica	Lee Biosolutions	• Price: Undisclosed • Status: Agreement to acquire 100% of Lee Biosolutions' shares with no closing date announced • Acquisition enables Medix to add high-quality biomaterials to complement its antibodies + antigens portfolio
Consortium led by private equity firms Cinven + Astorg	LGC	• Price: Undisclosed • Status: Agreement to acquire with no closing date announced • Acquisition of UK provider of reference materials, proficiency testing schemes, oligonucleotides, genomics reagents + instrumentation
Mesa Laboratories	Gyros Protein Technologies Holding	• Price: $180 million • Status: Closed • Mesa to make GPT core of its new biopharmaceutical development platform

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	Partner(s) 2+	Deal Summary
Prescient Metabiomics (Prescient Medicine Holdings subsidiary)	CoreBiome (OraSure Technologies subsidiary)	• Objective: Develop colon cancer screening test • Dynamic: Leverage CoreBiome's DNA sequencing platform to create test called LifeKit Prevent which will use microbial biomarkers to predict development of precancerous adenomas + carcinomas
Dolomite Bio	S2 Genomics	• Objective: Automate library preparation of tissue samples for single-cell RNA sequencing • Dynamic: Combine S2 Genomics' Singulator instrument for automated solid tissue preparation with Dolomite Bio's Nadia single-cell sample prep platform
Takeda Pharmaceuticals USA	MiTest Health	• Objective: Optimize MiTest personalized risk and outcome prediction tool for Crohn's disease • Dynamic: Exclusive partnership with Takeda to provide MiTest support in scaling up tool to expand its reach among gastroenterologists + patients
Takeda Pharmaceutical	Enzyre	• Objective: Develop home test that hemophilia patients can use to determine their coagulation status • Dynamic: Takeda to fund Enzyre's efforts to tailor its technology to enable automatic determination of coagulation status of hemophilic patients + transfer test results treating physicians via a mobile phone app

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	Partner(s) 2+	Deal Summary
Stratify Genomics	PWNHealth	• Objective: Offer Stratify's prostate cancer genetic risk test directly to consumers with medical oversight • Dynamic: Use Stratify online portal to offer latter's Prompt Personal Genetic Score (PGS) with PWNHealth to provide clinical oversight + patient support
Invitae	BioMarin Pharmaceuticals	• Objective: Expand access to genetic testing for skeletal dysplasias • Dynamic: Discover Dysplasias to offer free genetic testing to patients with symptoms of having a skeletal dysplasia • Invitae to provide testing + free genetic counseling • BioMarin to provide financial support to allow testing + counseling to be provided at no charge
Personalis	Merck KGaA	• Objective: Investigate new biomarkers of for use in cancer therapies • Dynamic: Merck to use Personalis' ImmunoID NeXT cancer immunogenomics platform to identify biomarkers, analyze therapy resistance mechanisms, stratify patients + study combination therapy strategies
Ontera	QuantuMDx	• Objective: Develop technology to detect bloodstream infections + drug-resistance • Dynamic: Technology to use QuantuMDx's rapid cell/sample preparation technology, Capture-XT + Ontera's nanopore biosensor
NeuMoDx Molecular	Sentinel Diagnostics	• Objective: Develop new molecular diagnostics assays • Dynamic: Combine technologies to create assays to detect + monitor post-transplant infections, parasitic, hospital-acquired + respiratory infections
Adaptive Biotechnologies	AbbVie	• Objective: Use NGS-based minimal residual disease testing in myeloma drug trials • Dynamic: Carry out multiple clinical trials in which AbbVie will use Adaptive's clonoSeq assay to assess MRD status in response to venetoclax, an inhibitor AbbVie is developing for multiple myeloma treatment
Royal Philips	Paige	• Objective: Provide clinical-grade AI technologies to pathology labs • Dynamic: AI technologies, including Paige Prostate software, designed to help pathologists identify, quantify + characterize cancer in tissue samples more efficiently
Ambry Genetics	Caris Life Sciences	• Objective: Provide genetic cancer testing in U.S. • Dynamic: Caris to offer Ambry's CancerNext-Expanded gene panel to evaluate hereditary risk of cancer alongside its own Caris Molecular Intelligence tumor profiling
Enpicom	Cytura Therapeutics	• Objective: Develop early cancer detection assay • Dynamic: Use sequencing- + machine learning-based methods to quantify genomic instability-causing mutations in blood cells

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Diagnostic Deals, *from page 5*

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	Partner(s) 2+	Deal Summary
Illumina	ArcherDx	• Objective: Develop NGS-based based in vitro diagnostic tests • Dynamic: ArcherDx to develop IVD test kits to run on Illumina's NextSeq 550Dx clinical sequencing system, including companion diagnostic tests for targeted therapy selection + monitoring minimal residual disease of patients with solid + blood tumors • ArcherDx responsible for commercializing + obtaining necessary regulatory approvals for each test kit
GenomSys	SysMeta IT	• Objective: Implement fledgling MPEG-G genomic data compression standard at Swiss labs + clinics • Dynamic: SysMeta IT to integrate GenomSys' MPEG-G tools into its Tangerine Medical software for viewing + annotating patient records + electronic ordering of sample analysis
Fujitsu Laboratories	Aichi Cancer Center	• Objective: Develop AI-based technologies for interpreting cancer genome data • Dynamic: Fujitsu to oversee database construction, integration of clinical and genomic profiles + development of patient diagnosis and drug selection technologies • Aichi to provide patient-specific genomic + medical data, advise on data interpretation + treatment selection for different cancers + verify technologies
Leica Biosystems	Sectra	• Objective: Develop an integrated clinical pathology solution + secure FDA Sec. 510(k) clearance • Dynamic: Combine Sectra's digital pathology software solution with Leica Bio's Aperio AT2 DX system
Indivumed	Biognosys	• Objectives: Add proteomic + phosphoproteomic data to Individumed's IndivuType multi-omics cancer database • Dynamic: Biognosys to use its mass spectrometry technology to profile proteome + phosphoproteome of clinical samples in Indivumed's database
HalioDx	OSE Immunotherapeutics	• Objective: Identify potential immune biomarkers for a non-small cell lung cancer treatment • Dynamic: HalioDx to test + analyze patient biopsy tissue samples for ongoing Phase III Atalante 1 clinical trial of OSE's neoepitope combination Tedopi
HalioDx	Kite Pharma	• Objective: Validate immune-based biomarkers for Kite's investigational therapies • Dynamic: Leverage HalioDx's Immunoscore immune-based tests

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	Partner(s) 2+	Deal Summary
Biolidics	Sysmex	• Objective: Develop liquid biopsy-based cancer test for Asian market • Dynamic: Continuation of collaboration began in 2016 to create liquid biopsy system combining Biolidics' ClearCell FX1 automated label-free circulating tumor cell separation + enrichment platform with Sysmex's MI-FCM molecular imaging flow cytometer system • Firms to jointly develop laboratory-developed test based on respective technologies • Biolidics to commercialize test in Asia (outside Japan) after clinical validation by its affiliate SAM Laboratory
Asuragen	Wave Life Sciences	• Objective: Develop companion diagnostics for Wave's investigational allele-selective therapeutic programs for Huntington's disease • Dynamic: Asuragen to use its AmplideX PCR technology to develop CDx based on SNP phasing methodology Wave is using in Huntington's clinical trials
Diagenode	Bio-Rad Laboratories	• Objective: Provide Diagenode's single-cell transposase accessible chromatin by sequencing (ATAC-seq) services on Bio-Rad's droplet digital PCR technology • Dynamic: Diagenode scATAC-Seq services to utilize Bio-Rad's ddSEQ Single-Cell Isolator to encapsulate thousands of cell nuclei or whole cells into nanoliter-sized droplets
Ikonisys	Sheba Medical Center	• Objective: Develop circulating tumor cell (CTC)-based diagnostics for different cancers • Dynamic: Sheba researchers to identify CTC-based biomarker panels for specific cancers, which will be evaluated as potential new Ikoniscope tests

DISTRIBUTION, SALES & MARKETING AGREEMENTS		
Product Owner	Distributor	Deal Summary
Spartan Bioscience	Angiocare	• Products: Spartan's CYP2C19 mutations tests • Territory: Netherlands but may expand to other territories
Magnolia Medical	Cardinal Health	• Products: Magnolia's Steripath Gen2 Initial Specimen Diversion Device • Territory: Not specified

LICENSES		
Licensor	Licensee	Deal Summary
Qiagen	LabCorp	• Extension of agreement covering Qiagen's Human Gene Mutation Database which LabCorp will use to improve identification + interpretation of genetic variants within inherited diseases

To read the rest of this story go to https://www.g2intelligence.com/diagnostic-deals-illumina-pacbio-merger-derails-qiagen-takes-itself-out-of-play/

Industry Buzz: The 10 Biggest DX Mergers of 2019

Conspicuous by its absence from the list is the proposed $1.2 billion Illumina takeover of Pacific Biosciences which suddenly seems to be in major trouble. (See DX Deals on page x for the details). Here are the 10-highest value M&A diagnostics deals that did come off in 2019.

Top 10 Lab M&A Deals of 2019

Rank	Buyer	Target	Reported Price
1	Danaher	GE Biopharma	$21.4 billion
2	Exact Sciences	Genomic Health	$2.8 billion (cash + stock)
3	Thermo Fisher Scientific	Brammer Bio	$1.7 billion
4	Agilent Technologies	BioTek Instruments	$1.17 billion
5	PHC Holdings (formerly known as Panasonic Healthcare Holdings)	Thermo Fisher Scientific	$1.14 billion
6	Sartorius	Danaher	$750 million*
7	Covance Drug Development (part of LabCorp)	Envigo	$485 million
8	Beckman Coulter Life Sciences	Labcyte	$308 million
9	PerkinElmer	Cisbio Bioassays	$219.8 million
10	Clayton, Dubilier & Rice investment funds	Cynosure (owned by Hologic)	$205 million

* Announced in 2019 with closing scheduled for 2020

FDA Watch: Agency Targets Sale of IVD Reagents without Premarket Approval

Distribution of diagnostics and devices without premarket approval has featured prominently on the FDA's enforcement priority list this year. The agency has issued seven warning letters related to premarket approval in 2019 after issuing just one such warning letter in all of 2018.

Carolina Liquid Chemistries was on the receiving end of the most recently announced warning letter, which contends that the Greensboro-based firm sold Class I and II in vitro diagnostic (IVD) reagents without obtaining the

necessary premarket approval. More specifically, Carolina Liquid failed to produce evidence showing that distributions of Tapentadol, Zolpidem, Spice and Fentanyl reagents branded only for forensic or research and development were restricted to appropriate research centers, law enforcement agencies or court mandated testing centers. The agency suspects that the reagents might have also been sold to pain management centers and a clinical testing laboratory for unapproved clinical testing applications. The FDA raised concerns about the sales history of Carolina Liquid reagents branded as for forensic and research use while inspecting the company's facilities last year.

New FDA Approvals

Here's a look at all the important new product approvals announced from mid-November through late December:

Manufacturer(s)	Product(s)
DiaSorin Molecular	Clearance for Simplexa VZV Swab Direct assay to detect varicella-zoster virus (VZV) DNA from cutaneous + mucocutaneous swab specimens
DiaSorin	Clearance for Simplexa VZV Swab Direct assay for qualitative detection of varicella-zoster virus DNA + use with firm's Liaison MDx instrument
Qiagen + DiaSorin	Clearance for Liaison QuantiFeron-TB Plus Test, an automated workflow and assay for latent tuberculosis detection
PerkinElmer	De novo premarket clearance for GSP Neonatal Creatine Kinase-MM kit for use in newborn screening for Duchenne Muscular Dystrophy
PerkinElmer	Clearance for GSP Neonatal Total Galactose kit for determination of total galactose concentrations in blood specimens dried on filter paper
Roche	De novo premarket clearance to market Cobas vivoDx MRSA test with Cobas vivoDx System
Seventh Sense Biosystems	Extension of existing 510(k) clearance for Tap push-button blood collection device, Tap, for use by laypersons and wellness testing at home
Sight Diagnostics	510(k) clearance for OLO finger prick blood tester
Personal Genome Diagnostics	Investigational Device Exemption (IDE) approval for use of its elio tissue complete assay in a Merck trial of pembrolizumab-based combination therapy
RightEye	Breakthrough device clearance for Parkinson's test
Foundation Medicine	Clearance for FoundationOne CDx test as a companion diagnostic for alpelisib (Novartis' Piqray) in combination with fulvestrant (AstraZeneca's Faslodex) for treatment of postmenopausal women, and men, with hormone receptor-positive, human epidermal growth factor receptor 2-negative, PIK3CA-mutated, advanced or metastatic breast cancer
BioMérieux	Clearance for received clearance for ETest Delafloxacin system
Beckman Coulter	Clearance for Access PCT chemiluminescent immunoassay for measuring procalcitonin levels using firm's Access immunoassay systems
Beckman Coulter	Clearance for MicroScan Dried Gram-Negative MIC/Combo Panels with Meropenem
Siemens Healthineers	Clearance for Advia Centaur Cortisol chemiluminescent immunoassay for quantitative determination of cortisol in serum, plasma and urine, using firm's Advia Centaur XP system

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FDA Watch, *from page 9*

Manufacturer(s)	Product(s)
Siemens Healthineers	Clearance for chemiluminescent Advia Centaur CA 15-3 assay to detect cancer antigen CA 15-3 in human serum and plasma using firm's Advia Centaur, Advia Centaur XP and Advia Centaur XPT systems
Immunalysis	Clearance Carisoprodol Metabolite/Meprobamate Urine HEIA enzyme immunoassay for analysis of anxiety disorder therapy meprobamate
Sebia	Clearance for Capi 3 Immunotyping kit for detection and characterization of monoclonal proteins in urine and serum

New CE Marks & Global Certifications

Notable European CE certifications announced during the period:

NEW CE MARKINGS IN EUROPE

Manufacturer(s)	Product(s)
Roche	CE marking for Accu-Check SugarView app, a blood glucose monitor designed to help non-insulin-dependent type patients manage type 2 diabetes between doctors' visits
Genematrix	CE marking for Neoplex RV-Panel A, a diagnostic kit to detect 10 major respiratory viruses
Nanomix	CE marking for mS1 Assay Panel and is used for simultaneous detection + quantification of lactate, procalcitonin + C-reactive protein associated with sepsis from human plasma specimens run on firm's eLab analyzer
Agilent Technologies	CE-IVD marking in Europe for PD-L1 IHC 22C3 assay for head + neck squamous cell carcinoma (HNSCC), a companion diagnostic in combination with Merck's anti-PD-1 immunotherapy pembrolizumab (Keytruda)
Genedrive	CE marking for Genedrive MT-RNR1 ID antibiotic-induced hearing loss test kit
T2 Biosystems	CE-IVD marking for T2Resistance Panel to detect genetic signatures of drug-resistant bacteria

Other international clearances announced during the period:

Manufacturer(s)	Country(ies)	Product(s)
Cytek Biosciences	China	National Medical Products Administration approval for seven Class I IVD flow cytometry reagents
Genetron Health	China	National Medical Products Administration approval for Genetron S5 instrument for targeted NGS based on Thermo Fisher Scientific Ion GeneStudio S5 system
Myriad Genetics	Japan	Ministry of Health, Labor and Welfare approval for BRACAnalysis Diagnostic System for identifying breast cancer patients with germline BRCA1 + BRCA2 mutations
CoSara Diagnostics (Co-Diagnostics' joint manufacturing venture)	India	Central Drug Standard Control Organization approval for 5 different CoSara Saragene molecular test kits (for detecting tuberculosis, malaria, hepatitis B + hepatitis C viruses, + human papillomavirus)

New Medicare Early NGS Cancer Test Coverage Policy Is Less than Meets the Eye, *from page 1*

for preventive screening and surgical interventions is less certain. With that in mind, CMS tried to pump the brakes by instructing Medicare Administrative Contractors (MACs) not to pay for such early-stage testing.

The New Coverage Proposal

But if the agency's idea was to fly under the radar, it didn't work. After a public outcry from industry and providers, CMS issued a new coverage proposal acknowledging the benefits and agreeing to pay for the testing. At first glance, the new proposal is a major reversal on germline NGS cancer testing coverage. In fact, it's anything but.

Problem 1: Just Ovarian & Breast Cancer

The first problem is that the proposal covers testing only for breast and ovarian cancer. Evidence supporting the use of germline NGS testing for pancreatic cancer, mesothelioma, astrocytoma and other inherited cancers is still limited, CMS claims. The silver lining: The agency acknowledges that the evidence of effectiveness of testing for other cancers "is rapidly developing" and gives the MACs discretion to make local coverage determinations on testing for cancers other than ovarian and breast as new evidence arises.

Problem 2: Coverage Conditions Are Too Strict

Medicare will only pay for NGS germline testing of early-stage cancer testing if five strict conditions are met:

1. The tests must be FDA-approved or -cleared and ordered for an approved or cleared indication.

2. The tests must be ordered by a treating physician.

3. The patient for whom the tests are ordered must have:

- Ovarian or breast cancer;
- Clinical indications for germline (inherited) testing;
- Risk factors for germline (inherited) breast or ovarian cancer; and
- Not been previously tested using NGS.

4. The ordered NGS test must generate results provided to the treating physician for management of the patient using a report template to specify treatment options.

5. The test must be performed by a CLIA-certified lab.

While the coverage criteria may look reasonable, there's not a single germline NGS test currently on the market that can meet them, advises reimbursement expert Bruce Quinn:

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New Medicare Early NGS Cancer Test Coverage Policy Is Less than Meets the Eye, *from page 11*

- Myriad Genetics' BRACAnalysis CDx is FDA-approved but isn't an NGS test;
- Myriad's NGS test myChoice CDx is FDA-approved for analyzing BRCA1/2 genes but is a somatic rather than a germline test;
- The Myriad MyRisk NGS panel is a germline test but hasn't been FDA-approved; and
- Foundation Medicine's FoundationOne CDx and FoundationFocus BRCA test are NGS and FDA-approved, but aren't germline tests.

Another problem pointed out by Quinn is the restriction that patients not have any prior NGS testing which excludes patients from getting germline testing after having previously received somatic NGS testing.

Takeaway: Whether deliberate or not, CMS' proposed new coverage policy continues to bar Medicare reimbursement for NGS germline cancer testing, even with regard to the applications it purports to cover.

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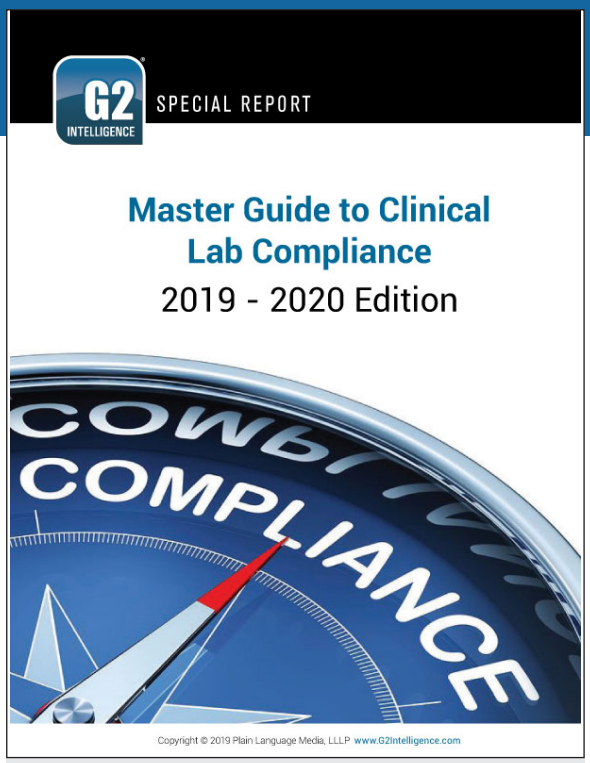

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