



Your Independent Source for Business & Financial News

LABORATORY

INDUSTRY REPORT™

Vol. 18, Iss. 12
December 2018



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Dealing with Consumers: Using Patient Online Reviews to Boost Your Lab Business

Patients are making increasing use of physician rating and review sites to comment on their medical experiences the way diners do with restaurants. And as with restaurants, this can be a tremendous boost or drag on your lab's business. Here's how to make effective use of these sites.

Continued on page 2

Case Studies: Lessons for Labs from the Memorial Sloan Kettering & Paige.AI Alliance

What began as an alliance benefiting both parties has turned into a controversy that has tainted the reputation of one of the nation's top research hospitals. Here's a quick recap of the story of Memorial Sloan Kettering Cancer Center and Paige.AI and the lessons it offers to labs regarding conflicts of interest, patient privacy and the other perils to consider in pursuing opportunities for outside income.

Paige.AI & MSK

Paige.AI is a startup whose mission, according to its website, is to help "pathologists to be more efficient, researchers to be more quantitative, and patients to be more confident in their diagnosis." Ultimately, Paige.AI aims to use artificial intelligence to one day change how cancer is diagnosed. These objectives made it naturally attractive to Memorial Sloan Kettering (MSK). The result was an exclusive licensing agreement between the two.

The idea of MSK's entering into such a commercial arrangement with a for-profit company didn't sit well with members of the medical community. Aggravating the problem is the fact that while Paige.AI operates as a separate company, it has close ties with its three founders' affiliations with the MSK Cancer Center among whom:

- ▶ One is director of the computational pathology lab;
- ▶ Another chairs the department of pathology; and

Continued on page 11

■ **Dealing with Consumers: Using Patient Online Reviews to Boost Your Lab Business, from page 1**

Top Review Sites

First, become familiar with the top healthcare review sites, which in no particular order, include:

- ▶ [Vitals](#)
- ▶ [Healthgrades](#)
- ▶ [RateMDs](#)
- ▶ [CareDash](#)
- ▶ [WebMD](#)

Ideally, the more information a site provides, the better.

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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.

Formats

Each site is slightly different. At Vitals, for example, healthcare providers are rated using stars in seven categories. Individual rating categories are shown, as is a total rating. Site users may also share wait time. In addition, there is a comment section.

The number of categories and information vary at Healthgrades, RateMDs, and CareDash. Each of these sites allows for comments.

At WebMD, there are multiple rating categories, although no comment section.

At all sites, individual site user ratings add up to an overall rating.

Ideally, the more information a site provides, the better. Nevertheless, it's worth keeping an eye on all these sites, as they are all popular and therefore valuable resources.

What to Look for

Star ratings are obviously an area on which you want to focus. Keep in mind, however, that a bad review can skew an overall rating. Such is the case with a pathologist rated at Healthgrades who received one five-star review and one one-star review.

In addition to ratings, pay attention to comments. At Vitals, for example, one reviewer had this to say about a pathology specialist: "She was arrogant and has no bedside manner."

Here again, weigh negative comments in relation to overall feedback. One bad experience isn't likely to impact your business. On the other hand, multiple negative comments suggest a pattern. In conducting research for this article, National Intelligent Report found several pathologists with numerous negative comments.

While the patient experience matters, so do other categories. Don't overlook business basics. At Vitals, categories include friendly staff. At Healthgrades, site users rate office environment. CareDash includes communication.

What adds up to best practices? These sites will give you some insight—while pointing out areas where your lab may want to make improvements. 

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

As the year winds down, diagnostic deals aren't as plentiful. Nevertheless, there have been some significant transactions. Here's a recap of the key activity from mid-October through the third week of November. .

M&A and Asset Sales

The biggest deal in recent weeks also happens to be one of the year's biggest. Illumina will acquire Pacific Biosciences for approximately \$1.2 billion in cash. Under the agreement, which has been approved by the boards of directors of both companies, Illumina will pay \$8.00 per PacBio share. This represents a 71% premium over PacBio's 30 trading-day volume weighted average share price as of the market close on Oct. 31.

Illumina is willing to pay a premium to gain access to PacBio's long-read sequencing technology and potential clinical applications, as it will extend Illumina's reach into areas such as de novo assembly of plant and animal genomes, functional genomics, tissue transplantation, and pharmacogenomics. The long-read sequencing market, estimated at \$600 million in 2017, is expected to increase to \$2.5 billion by 2022.

In other news, Quest Diagnostics will acquire Marin General Hospital's outreach lab services operations for an undisclosed amount. Quest has also closed on the previously reported acquisition of Oxford Immunotec Global. This makes it a busy fall for Quest; last month, the company was involved in five other deals.

Strategic Alliances

Speaking of busy, among the alliances announced this past month is one involving Illumina. The company will partner with Blue Cross Blue Shield Association to further the understanding of precision medicine in the United States. The plan is to create a report on availability and clinical understanding of DNA sequencing technologies, genetic testing, and precision medicine that will prove—pardon the pun—Illumina-ting.

In other news, Google is on this month's radar. IntegraGen has entered into a partnership with Google Cloud. The company aims to promote use of personalized medical care by facilitating genomics research projects and analysis of sequencing data by integrating its Sirius and Mercury genomic analysis tools into Google Cloud Platform.

These and other alliances, including a noteworthy partnership between 23andMe and MyoKardia, are detailed in the chart below.

Here's a summary of key diagnostic deals from late October through the third week in November:



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MERGERS, ACQUISITIONS & ASSET SALES		
Acquiring Company	Target(s)	Deal Summary
Illumina	Pacific Biosciences	<ul style="list-style-type: none"> Price: \$1.2 billion cash (\$8 per share, representing 71% premium over market for 30 days ending Oct. 31) Status: Agreement approved by boards of both companies to close in mid-2019 PacBio long-read sequencing technology complements Illumina short-read sequencing platforms and enables it to provide integrated workflows and innovations that leverage both technologies
Quest Diagnostics	Oxford Immunotec Global	<ul style="list-style-type: none"> Price: \$170 million cash Status: Closed 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 but keep T-SPOT.CMV and C6 Lyme ELISA assay kit Sides to enter strategic agreement to grow T-Spot.TB testing in US
Quest Diagnostics	Marin General Hospital	<ul style="list-style-type: none"> Price: Undisclosed Status: To close by end of 2018 Quest acquires non-profit hospital's outreach lab services operations
BioMérieux	Suzhou Hybiome Biomedical Engineering	<ul style="list-style-type: none"> Price: Undisclosed Status: Closed BioMérieux acquires 54% of Chinese immunoassay firm after acquiring minority stake in July
NeoGenomics	Genoptix	<ul style="list-style-type: none"> Price: \$125 million cash + 1 million shares NeoGenomics stock Status: Definitive agreement with no closing date announced Acquisition of clinical oncology lab boosts NeoGenomics' heretofore limited ties to community oncology practices
Chembio Diagnostics	OpTricon	<ul style="list-style-type: none"> Price: \$5.5 million cash Status: Expected to close in 2018 Since 2015, companies have collaborated to develop DPP Micro Reader, handheld, battery operated analyzer that uses an image sensor to quantitatively interpret diagnostic results when combined with Chembio's DPP tests
Bruker	Hain Lifescience	<ul style="list-style-type: none"> Price: Undisclosed Status: Closed Bruker acquires 80% stake in German molecular diagnostics firm with option to acquire remaining 20%
Progentec Diagnostics	LupusCorner	<ul style="list-style-type: none"> Price: Undisclosed Status: Closed Progentec acquires health management platform for systemic lupus erythematosus and lupus nephritis patients
Medicover	Invitro	<ul style="list-style-type: none"> Price: \$6.9 million cash Status: Expected to close in 2018 Poland-based Medicover to acquire Invitro's Ukrainian lab operations with both businesses to be consolidated in 2019



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Lab Compliance Essentials 2017: Managing Medicare Fraud & Abuse Liability Risk

Avoid catastrophic financial fines and penalties! Whether you're a large laboratory with a robust compliance program and legal counsel on staff, or a small-to-mid size pathology group faced with navigating these murky waters alone, this guide delivers exclusive market intelligence and insight into compliance risks faced by labs and pathologists, while providing direction and guidance on how to minimize these risks.

Contact Myra at **1-888-729-2315** or Myra@PlainLanguageMedia.com for details on this special offer.

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	Partner 2	Deal Summary
IntegraGen	Google Cloud	<ul style="list-style-type: none"> Objective: Promote use of personalized medical care by facilitating genomics research projects and analysis of sequencing data Dynamic: Integrate IntegraGen's Sirius and Mercury genomic analysis tools into Google Cloud Platform
Illumina	Blue Cross Blue Shield Association	<ul style="list-style-type: none"> Objective: Enhance understanding of the state of precision medicine in US Dynamic: By early 2019, create report on availability and clinical understanding of DNA sequencing technologies, genetic testing and precision medicine
Sophia Genetics	Paragon Genomics	<ul style="list-style-type: none"> Integrate Paragon Genomics' CleanPlex NGS target enrichment technologies into Sophia AI platform
OpGen	Qiagen	<ul style="list-style-type: none"> Objective: Offer Qiagen nucleic acid purification technology with OpGen's Acuitas antimicrobial resistance detection panel Dynamic: OpGen to purchase Qiagen's EZ1 Advanced XL automated nucleic acid purification instruments and reagent kits and offer them for use with its research-use-only Acuitas AMR Gene Panel u5.47 for detecting multidrug-resistant bacterial pathogens in urine or bacterial isolates
Thermo Fisher	Symphogen	<ul style="list-style-type: none"> Objective: Develop validated platform workflows to monitor quality of complex therapeutic proteins Dynamic: Under 2-year agreement, Symphogen to use Thermo Scientific Q Exactive Plus Orbitrap liquid chromatography tandem mass spectrometry system with BioPharma Option to create platforms for analyzing therapeutic monoclonal antibody mixtures
NanoString	MacroGenics	<ul style="list-style-type: none"> Objective: Develop biomarkers for MacroGenics' MGD013 program Dynamic: Joint research using NanoString PanCancer IO 360 panel to identify potential signatures for MGD013
Precipio	PerkinElmer	<ul style="list-style-type: none"> Jointly offer Precipio's ICE COLD-PCR (ICP) mutation enrichment technology with PerkinElmer's NextPrep-Mag cell-free DNA isolation kit, Janus G3 liquid handling workstation and Chemagic MSM I, Chemagic 360, and Chemagic Prime platforms
Leica Biosystems	Ultivue	<ul style="list-style-type: none"> Objective: Comarket each company's biomarker detection products Dynamic: Market Ultivue's UltiMapper assays together with Leica's Bond Rx research staining platform
Siemens Healthineers	Healthy.io	<ul style="list-style-type: none"> Objective: Market smartphone system for home monitoring of chronic kidney disease Dynamic: Global original equipment manufacturer alliance integrating Siemens Healthineers urinalysis reagents into Healthy.io's smartphone-based urinalysis system
23andMe	MyoKardia	<ul style="list-style-type: none"> Objective: Advance hypertrophic cardiomyopathy (HCM) research Dynamic: Create patient community that 23andMe customers can use to access regularly updated HCM information
SeraCare Life Sciences	AccuRef Diagnostics	<ul style="list-style-type: none"> Objective: Market AccuRef's CRISPR-engineered cell line reference materials Dynamic: SeraCare to sell AccuRef materials in all markets but China
Invitae	Alnylam Pharmaceuticals	<ul style="list-style-type: none"> Objective: Offer free genetic testing to improve diagnosis and management of primary hyperoxaluria Dynamic: Tests must be ordered by MDs with Invitae to provide test results in 2 weeks without giving Alnylam access to identifiable patient information
Berry Genomics	Prenetics	<ul style="list-style-type: none"> Objective: Offer direct-to-consumer genetic testing services in Chinese market Dynamic: Create joint venture to sell integrated digital health and genetics testing services directly to consumers in mainland China
BGI	Fred Hutchinson Cancer Research Center	<ul style="list-style-type: none"> Objective: Work together on cancer genomics, immunology and infectious disease projects Dynamic: Leverage BGI's sequencing technology and Hutchinson's cancer research and analysis expertise
BioLegend	VIB	<ul style="list-style-type: none"> Objective: Deploy single-cell multi-omics technology Dynamic: Test and deploy BioLegend's TotalSeq antibodies as part of workflow combining single-cell proteomics with single-cell transcriptomics

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS		
Partner 1	Partner 2	Deal Summary
Oxford BioDynamics	Casa Sollievo della Sofferenza	<ul style="list-style-type: none"> Objective: Identify blood-based biomarkers of autism spectrum disorder Dynamic: Develop autism biomarker assay based on Oxford BioDynamics' EpiSwitch platform for discovery, evaluation, validation, and monitoring of chromosome conformation signatures
Almac Diagnostic Services	TP Therapeutics	<ul style="list-style-type: none"> Objective: Develop NGS companion diagnostic for TP's repotrectinib, an investigational tyrosine kinase inhibitor Dynamic: Almac to develop test based on tArcherDx Anchored Multiplex PCR chemistry and seek US regulatory approval
Quanterix	OncoGenesis	<ul style="list-style-type: none"> Objective: Develop protein biomarker test for cervical disease Dynamic: Use Quanterix's SP-X Imaging and Analysis system to create test OncoGenesis to handle commercialization of test
RTI	Asuragen	<ul style="list-style-type: none"> Objective: Perform high-throughput screening testing for fragile X syndrome in newborns Dynamic: Screening to be conducted using Asuragen's technology via North Carolina's free Early Check study to identify children with rare health conditions before symptoms develop
Natera	Neon Therapeutics	<ul style="list-style-type: none"> Use Natera's Signatera circulating tumor DNA assay to assess treatment response to NEO-PV-01, a clinical trial-stage neoantigen cancer vaccine
OneOme	Catherine Specialty Hospital	<ul style="list-style-type: none"> Offer OneOme's PGx testing to patients of hospital (located in Croatia)

DISTRIBUTION, SALES & MARKETING AGREEMENTS		
Property Owner	Distributor	Deal Summary
Syntec	Bioké	<ul style="list-style-type: none"> Products: Syntec's Medimachine semi-automated homogenizer products Territory: Netherlands, Belgium, Luxembourg Exclusive
Guardant Health AMEA	Core Diagnostics	<ul style="list-style-type: none"> Products: Guardant's Guardant360 comprehensive liquid biopsy test Territory: India Expansion of exclusive distribution deal from five to eight years following first Chinese regulatory approval
SpeedX	Axonlab	<ul style="list-style-type: none"> Products: ResistancePlus GC, ResistancePlus MG and other SpeedX tests Territory: Germany, Belgium, Netherlands, Luxembourg, Switzerland
SpeedX	Vircell	<ul style="list-style-type: none"> Products: ResistancePlus GC, ResistancePlus MG and other SpeedX tests Territory: Spain
SpeedX	Diamedica	<ul style="list-style-type: none"> Products: ResistancePlus GC, ResistancePlus MG and other SpeedX tests Territory: Estonia, Latvia, Lithuania
SpeedX	Biomedica	<ul style="list-style-type: none"> Products: ResistancePlus GC, ResistancePlus MG and other SpeedX tests Territory: Central Eastern Europe
Dovetail Genomics	Premas Life Sciences	<ul style="list-style-type: none"> Products: Dovetail's genomics products and services Territory: India
Dovetail Genomics	Millennium Science	<ul style="list-style-type: none"> Products: Dovetail's genomics products and services Territory: Australia and New Zealand
Dovetail Genomics	Ultravision Technology + Shanghai Biozeron Biotechnology	<ul style="list-style-type: none"> Products: Dovetail's genomics products and services Territory: China

DISTRIBUTION, SALES & MARKETING AGREEMENTS		
Property Owner	Distributor	Deal Summary
Dovetail Genomics	Genomics Bioscience	<ul style="list-style-type: none"> Products: Dovetail's genomics products and services Territory: Taiwan
Dovetail Genomics	Bio-Active	<ul style="list-style-type: none"> Products: Dovetail's genomics products and services Territory: Thailand
Dovetail Genomics	Biomedical Science Material	<ul style="list-style-type: none"> Products: Dovetail's genomics products and services Territory: Vietnam
Karius	Dasa	<ul style="list-style-type: none"> Products: Karius's NGS-based infectious disease test Territory: Brazil
OncoDNA	Gammaray Private Health Services	<ul style="list-style-type: none"> Products: OncoDNA's molecular profiling tests Territory: Turkey
OncoDNA	AMS 2000 Trading Impex	<ul style="list-style-type: none"> Products: OncoDNA's molecular profiling tests Territory: Romania

LICENSES		
Licensor	Licensee	Deal Summary
Expedeon	Quanterix	<ul style="list-style-type: none"> Property: CaptSure immunoassay products + Lightning-Link antibody labeling tech Non-exclusive
ERS Genomics	DefiniGen	<ul style="list-style-type: none"> Property: CRISPR-Cas9 genome editing tech DefiniGen to combine with its stem cell differentiation platform to generate preclinical cell models for type 2 diabetes, rare liver diseases and non-alcoholic fatty liver disease drug discovery
Broad Institute	DefiniGen	<ul style="list-style-type: none"> Property: CRISPR-Cas9 genome editing tech For use in developing human cell disease models
Co-Diagnostics	LGC Biosearch Technologies	<ul style="list-style-type: none"> Property: CoPrimer PCR technology Exclusive for research and commercial applications in agriculture
XCR Diagnostics	Luminex	<ul style="list-style-type: none"> Property: XCR's Xtreme Chain Reaction nucleic acid amplification technology Non-exclusive
National University of Singapore	Proteona	<ul style="list-style-type: none"> Property: Sequencing-based protein analysis technology Global exclusive

SUPPLY, SERVICE & TESTING AGREEMENTS		
Supplier/Service	Client	Deal Summary
LabCorp	Horizon Blue Cross Blue Shield of New Jersey	<ul style="list-style-type: none"> Renewal of lab services agreement but LabCorp no longer exclusive provider
Quest	Horizon Blue Cross Blue Shield of New Jersey	<ul style="list-style-type: none"> Addition of Quest as lab services provider, a status previously reserved exclusively to LabCorp
Clinical Genomics	Quest	<ul style="list-style-type: none"> 5-year extension of US supply agreement for InSure One fecal immunochemical test (FIT)
Stratec Consumables	Vortex BioSciences	<ul style="list-style-type: none"> Stratec to provide materials for use in creating microfluidic chip used in Vortex's VTX-1 Liquid Biopsy System

FDA Watch: First NGS Residual Cancer Detection Test Wins Approval

The FDA broke new ground by allowing marketing of Adaptive Biotechnologies' ClonoSEQ assay, a next generation sequencing (NGS)-based test for minimal residual disease (MRD) in patients with acute lymphoblastic leukemia (ALL) or multiple myeloma.

PCR v. NGS

MRD is a general measure of the amount of cancer in the body (tumor burden), specifically the number of cancer cells that remain in a person's bone marrow, either during or after treatment. Measuring MRD provides a tool to detect very low levels of tumor burden. MRD is useful to evaluate in patients who have responded to therapy when their tumor burden is below what can be detected with standard methods. The detection of MRD is associated with recurrence of the disease in those patients. Currently, providers test for MRD using diagnostics called flow cytometry assays or polymerase chain reaction (PCR)-based assays. Those methods are usually capable of measuring MRD down to 1 in 10,000 or 1 in 100,000 cells.

By contrast, ClonoSEQ is an *in vitro* diagnostic that uses multiplex PCR and NGS to identify and quantify certain gene sequences in DNA extracted from bone marrow from patients with ALL or multiple myeloma. The ClonoSEQ assay measures the amount of MRD and is capable of detecting MRD at levels below 1 in 1 million cells.

New FDA Approvals

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

NEW FDA APPROVALS

Manufacturer(s)	Product(s)
Becton Dickinson	Clearance for BD Phoenix CPO test
BioFire Diagnostics	510(k) clearance for PCR-based panel to detect 33 common pathogens causing lower respiratory tract infections
Siemens Healthineers	Breakthrough Device designation for Advia Centaur Enhanced Liver Fibrosis (ELF) test
PixCell Medical	Approval for marketing HemoScreen Hematology Analyzer
Ortho Clinical Diagnostics	Approval of Vitros Immunodiagnostic Products HIV Combo Reagent Pack and Calibrator for use on Vitros 5600 Integrated System
Ortho Clinical Diagnostics	Clearance for Vitros XT 7600 Integrated System
23andMe	Authorization to sell tests for 33 pharmacogenetic variants directly to consumers
EliTech Group	510(k) clearance for ELiTe MGB HSV 1&2 Assay and Elite InGenius instrument
Aptatek BioSciences	Breakthrough Device designation for phenylketonuria (PKU) test system
Bio-Rad Laboratories	510(k) clearance for (BIO +1.1%) IH-Reader 24, semi-automated blood typing system
Abbott	Clearance for NGS Influenza A & B 2 and Strep A 2 molecular assays for point-of-care testing

Manufacturer(s)	Product(s)
Ansh Labs	Clearance for PicoAMH ELISA diagnostic test as an aid in determining a patient's menopausal status
Inova Diagnostics	Clearance for fecal extraction device for use with the firm's Quanta Flash Calprotectin assay
LabCorp	Clearance for Extended Lipid Panel Assay for quantitative determination in human serum and plasma of total cholesterol, HDL cholesterol and triglycerides running on LipoScience Vantera Clinical Analyzer
Sysmex	Clearance for UD-10 Fully Automated Urine Particle Digital Imaging Device
Diazyme Laboratories	Clearance for enzymatic assay for detection of 1,5- anhydroglucitol for intermediate monitoring of glycemic control of patients with diabetes
Phamatech	Clearance for QuickScreen Pro Multi Drug Screening test for drugs of abuse
Binding Site Group	Clearance for Optilite High Sensitivity C-Reactive Protein kit
Immunalysis E	Clearance for Ethyl Alcohol Enzyme Assay for analysis of ethyl alcohol or ethanol with automated clinical chemistry analyzers
Immuno Concepts	Clearance for Histofluor Rodent LKS Fluorescent Antibody Test System for detection of IgG autoantibodies

New CE Marks & Global Certifications

Notable European CE certifications:

NEW CE CERTIFICATIONS IN EUROPE

Manufacturer(s)	Product(s)
Mesa Biotech	CE marking for Mesa RSV molecular diagnostic assay to detect respiratory syncytial virus
Quotient	CE marking for MosaiQ instrument
RPS Diagnostics	CE marking for updated FebriDx test for identifying clinically significant underlying febrile acute respiratory infections
PlexBio	CE marking for IntelliPlex Lung Cancer Panel molecular diagnostic assay for qualitative identification of 36 DNA mutations
MRC Holland	CE-IVD marking for SALSA MC002 assay for spinal muscular atrophy (SMA) screening in newborns

Other international clearances announced in the past month:

Manufacturer(s)	Product(s)	Product(s)
Asuragen + MolecularMD	Canada	Health Canada approval for BCR-ABL tests for use in chronic myeloid leukemia (CML) patients
MolecularMD	Canada	Health Canada approval for PCR-based MRDx BCR-ABL test as aid to monitor TKI treatment in Philadelphia chromosome positive CML patients
Illumina	Japan	Pharmaceuticals and Medical Devices Agency approval for NextSeq 550Dx sequencing platform
Agena Biosciences + DaRui Biotechnology	China	China Food and Drug Administration approval for Agena's MassArray system
Zeesan Biotech	China	China Food and Drug Administration approval for MeltPro High Risk HPV test

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)
Quest	QuestDirect, consumer-initiated testing service empowering patients to order health and wellness lab testing from home
LabCorp	Pixel by LabCorp, consumer-initiated wellness testing and personalized online results
Hologic	Open Access functionality allowing CLIA-certified labs to develop LDTs to run on firm's Panther Fusion platform
NanoString Technologies	nCounter(R) CAR-T Characterization Panel for molecular characterization of CAR-T cells
Arima Genomics	Arima-HiC sample preparation kit
10x Genomics	Single Cell ATAC Solution enabling researchers to analyze open chromatin regions in single cells
10x Genomics	Feature Barcoding for simultaneous, same cell analysis of specific biological components and gene expression
Qiagen	GeneRead QiaAct Actionable Insights Tumor DNA UMI panel
Qiagen	GeneRead QiaAct BRCA Advanced UMI panel
Qiagen	QiaSeq TMB Panel
Qiagen	DNeasy Plant Pro Kit for extraction of high-quality DNA from varied plant samples
Biocrates Life Sciences	MxP Quant 500 system for quantitative measuring of different metabolites produced by intestinal bacteria
Vela Diagnostics	Great Basin's infectious disease diagnostic system
Vela Diagnostics	New version of Sentosa SQ HCV Genotyping Assay
Horizon Discovery	Set of precisely defined cell line-derived reference standards supporting Biocartis' Idylla microsatellite instability (MSI) Assay
Agena Bioscience	Chimeric ID Panel for chimerism analysis in bone marrow engraftment monitoring studies (research only)
NeuMoDx Molecular	NeuMoDx 288 Molecular System and NeuMoDx 96 Molecular System
Agilent Technologies	Agilent OnePGT, genome-wide, NGS solution for preimplantation genetic testing
Uromonitor	Uromonitor, genetic test for detecting bladder cancer recurrence
Menarini Silicon Biosystems	DepArray FFPE SamplePrep Kit
Illumina	TruSight Oncology 500 (TSO 500) pan-cancer assay
Rheonix	NGS OnePrep solution for DNA extraction and NGS library preparation on the Encompass Optimum workstation

Company(ies)	Product(s)
Cofactor Genomics	ImmunoPrism Immune Profiling, RNA-based kit for deriving immune composition of tumor samples
Sirona Dx	Oncocyst PD-L1 assay
DiaCarta	Line of TaqMan qPCR assays using firm's QClamp XNA-based technology
CooperSurgical Fertility and Genomic Solutions	CooperGenomics PGTai technology platform
CooperSurgical Fertility and Genomic Solutions	ERPeak endometrial receptivity test
MGI (subsidiary of BGI Group)	MGISEQ-T7 sequencing platform
MGI (subsidiary of BGI Group)	MGISP-960, automated sample preparation system
Celsee	Genesis single-cell analysis platform
SeraCare Life Sciences	Expanded neurotrophic tropomyosin receptor kinase (NTRK) RNA fusion material panel developed in partnership with Bayer
Cytek Biosciences	Northern Lights flow cytometry system
Lucence Diagnostics	LiquidHallMark blood test for detecting multiple cancer-related mutations and viral targets for clinical use in Asia
Almac Diagnostic Services	claraT, a software tool for classifying biologically relevant gene expression signatures into comprehensive report

■ **Case Studies: Lessons for Labs from the Memorial Sloan Kettering & Paige.AI Alliance, from page 7**

- ▶ The third is on the MSK board of trustees and executive committee.

In addition, three other MSK board members have also invested in Paige.AI. MSK also holds an equity stake in the company.

Potential Conflicts of Interest

Because of their close ties, the arrangement between the parties has raised conflict of interest red flags among at least some MSK doctors and scientists from the beginning. Recent investigative reporting by ProPublica and *The New York Times* shows that these concerns have become deeper and spread to other business arrangements. Thus, MSK's chief medical officer recently resigned because of failure to disclose financial ties to companies cited in his research articles.

Patient Privacy

Meanwhile, the negative publicity from this reporting has been internally disruptive and caused pathologists and others to step forward and voice their concerns about the Paige.AI arrangement. Among these concerns is patient privacy. MSK has reportedly licensed images of 25 million patients' tissues slides and the hospital's pathologists' library of past work to Paige.AI.

Doctors have raised questions about whether patients consented to having their tissue used in this way. A hospital review board initially indicated that the issue was addressed via securing patient consent regarding overall information sharing. More recently, however, MSK has taken what appears to be a different position by calling attention to “information that was not clear in recent news stories.” A detailed statement at its [website](#) reads, “No patient tissue, patient slides, or protected health information has been or will be shared with Paige.AI. The patient slides are stored and remain in MSK’s possession.”

Non-Profit Issues

Experts in nonprofit law and corporate governance have also expressed concerns about the arrangement, according to *The New York Times* and ProPublica. Experts questioned “whether Memorial Sloan Kettering, which is a charity, acted properly in what is known as a related party transaction with the founders of Paige.AI.” Among the issues is that “charitable institutions like Memorial Sloan Kettering must show they didn’t provide assets to insiders for less than the fair market value.”

Clearly, there are numerous considerations when entering into a licensing agreement. The MSK agreement with Paige.AI serves as a cautionary tale. **G2**

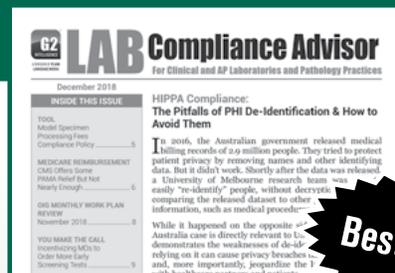


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