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IN THIS ISSUE

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Economic Trends: Labs Lost Less & Will Recover More than Other Healthcare Sectors, Says New Report

Although it's not exactly "Happy Days Are Here Again," a new S&P report is predicting that the healthcare sector has seen the worst of the COVID-19 pandemic and won't have to go through "a return to the lows of earlier stages of pandemic in late March/early April." However, the report also says a full rebound to pre-pandemic levels probably won't happen until a coronavirus vaccine becomes available.

Not as Bad for Labs as It Was for Other Sub-Sectors

The economic devastation that COVID-19 wrought on healthcare was unprecedented,

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Genomic Testing: Utilization Is Low & Geographically Inconsistent but Not Just Due to Payor Coverage

Genomic testing is inconsistently utilized in the U.S., even in states with favorable coverage policies. Those are the findings of a report from the Personalized Medicine Coalition (PMC) released in early August. Conducted in partnership with the Blue Cross Blue Shield Association, Concert Genetics and Illumina, the project analyzed trends and potential barriers to genomic testing access and utilization across the U.S. While wide variation and lack of clarity in payer coverage policies present barriers to genomic testing, the report found that there may be other factors preventing greater adoption of such testing.

The Diagnostic Challenge

Because no two people are exactly the same, medical management must be personalized can't

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Economic Trends: Labs Lost Less & Will Recover More than Other Healthcare Sectors, Says New Report, *from page 1*

according to the report, with outpatient surgeries declining by as much as 90 percent and hospital admissions dropping 60 percent. Physical therapy, home healthcare and dental services were also among the hardest hit. S&P doesn't expect a full recovery for these sub-sectors until 2022.

Labs got off relatively easy, the report finds. In fact, diagnostics, lab testing and life sciences actually posted net gains during the pandemic. Of course, those gains are disproportionate and belie the losses suffered by the majority of labs not in the molecular or respiratory virus testing space. Still, S&P expects these sub-sectors to get back to near pre-pandemic levels by the end of *this year*, with no impact to their general credit ratings.

The Shape of Recovery

Although the recovery has already begun, the report notes that it has been largely V-shaped, with hospital admissions back to within 10% of pre-pandemic levels and outpatient surgeries almost back to normal. But the assumption underlying the optimism about patients getting back to receiving the care they deferred during the pandemic remains unproven. And even if the assumption is right, the surge is likely to ebb once everybody gets caught up.

Meanwhile, the increasing numbers of uninsured—which stands at roughly 33.5 million, including the at least 5.4 million Americans who lost their health insurance due to COVID-19 job losses and economic dislocation—could prove to be the fly in the ointment. "The adverse change in payors mix and likely increase in charity care will mean greater uncertainty for healthcare providers," the report notes. "And while healthcare is largely insulated from economic downturns, the pandemic has highlighted the still significant discretionary aspects of healthcare. How the recession and unemployment colors the healthcare discussion in Washington remains to be seen."

Grounds for Optimism in Lab Testing

S&P expects the increase in demand for COVID-19 testing and testing products to continue for at least several more quarters. These gains will come at the same time as increases in testing for elective surgeries and widespread COVID-19 screening of the asymptomatic in schools, workplaces and other settings undergoing reopening. And, if and when a vaccine does become available, lab companies will once more benefit from the massive demand for testing necessary to produce the billions of doses that will be needed.

The cloud to this silver lining remains the downward pressures on reimbursement rates for lab testing from not only Medicare and Medicaid due to PAMA, but also private sector payors.

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Takeaway

"It's not the beginning of the end, but it may be the end of the beginning."

Winston Churchill uttered those words after General Montgomery's 8th Army defeated Rommel's Afrika Korps at the November 1942 Battle of El-Alamein, marking Britain's first major land battle victory of the Second World War. And while there would be nearly three more years of blood, sweat and tears to shed, Churchill turned out to be right.

The S&P report comes to a largely equivalent prediction as far as healthcare sector economic recovery goes (although the prognostications for labs, diagnostics and life sciences are far more rosy than for other sub-sectors). Here's to hoping that the new report coming to the similar conclusion with regard to the economic tribulations caused by the COVID-19 pandemic proves just as prophetic.

M&A Report: Re-Acquisition of Grail to Boost Illumina's Cancer Presence, but Investors Are Skeptical

M&A activity during the time of COVID-19 has been notable for two and largely incongruous characteristics: scant numbers of overall deals and unexpected, rather curious blockbusters. A month after the cratering of the Thermo Fisher Scientific takeover of Qiagen, those patterns continued in September with low volume and the announcement of Illumina's planned $8 billion acquisition of Grail.

Illumina to Reacquire Grail

On Sept. 21, Illumina announced that it had signed a definitive agreement to acquire its Grail, the liquid biopsy firm it spun off in 2016 spinoff and which had announced its own plans to go public just a week earlier. The price: $3.5 billion in cash and $4.5 billion in shares of Illumina common stock. Under the acquisition agreement, which has been approved by each company's board of directors, Grail shareholders, who include **Bill Gates** and **Jeff Bezos**, will also get payments of 2.5% off the first $1 billion of Grail-related revenues and 9% off revenues above $1 billion per year over 12 years. When and if the deal closes, which is expected to happen in the second half of next year, Illumina shareholders would own about 93% percent of the combined company.

The deal will enable Illumina to expand its position in the cancer diagnostics market. Grail is planning a 2021 launch of a highly touted blood-based screening test called Galleri that uses methylation sequencing for ultra early detection of over 50 different types of cancers. Illumina president and CEO's statement described Galleri as being "among the most promising new tools in the fight against cancer," and

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M&A Report: Re-Acquisition of Grail to Boost Illumina's Cancer Presence, but Investors Are Skeptical, *from page 3*

said that the acquisition would help Illumina "transform cancer care using genomics and our NGS platform." Illumina, which currently owns 12% of its former spinoff, is also the supplier of the sequencers that Grail uses for performing its genomic tests. Bringing the two companies back together would put the testing and sequencing under one roof.

However, investors were far less excited. After rumors of the buyback drove Illumina share prices down about 11%, announcement of the actual deal caused another decline of 4.5% to $282.14 per share on the Nasdaq market. Investor concerns were based on the high purchase price and potential distraction from Illumina's core business. "We don't see a clear fit for acquiring a company that (a) is still at a stage where clinical studies and clinical product development are still critical and will be for years, and (b) would benefit from true clinical commercial infrastructure/reach that does not really exist at Illumina," noted Cowen & Co. analyst **Doug Schenkel**, as cited in a report from GenomeWeb.

Qiagen Buys the Rest of NeuMoDx Molecular

The second most impactful M&A transaction in a month with fewer than half a dozen deals involved the same firm that made headlines last month when its shareholders rejected a tender offer from Thermo Fisher Scientific. On Sept. 17, Qiagen announced its acquisition of the remaining 80% of NeuMoDx that it didn't already own for $248 million in cash. The purchase represents an exercise of the option the molecular testing company acquired when it bought a 19.9% stake in NeuMoDx. Qiagen currently distributes the high-throughput NeuMoDx 288 and medium-throughput NeuMoDx 96 diagnostic testing platforms in Europe and other markets outside the U.S. NeuMoDx has also received FDA clearance for a group B *Streptococcus* test on the platforms. A new multiplex test for influenza, respiratory syncytial virus (RSV), and SARS-CoV-2 is scheduled for launch in the fourth quarter of 2020.

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Here's a summary of the key M&A diagnostic deals announced in September 2020:

MERGERS, ACQUISITIONS & ASSET SALES

Acquiring Company	Target(s)	Deal Summary
Illumina	Grail	• Price: $8 billion, including $3.5 billion cash + $4.5 billion shares of Illumina common stock; Grail shareholders to also get payments of 2.5% off first $1 billion of Grail revenue + 9% off revenues above $1 billion per year over 12 years • Status: Expected to close in 2021 • Acquisition of former Illumina spinoff, which Grail will operate as standalone division within Illumina and keep its own leadership team

Acquiring Company	Target(s)	Deal Summary
Qiagen	NeuMoDx Molecular	• Price: $248 million in cash to acquire the roughly 80% of NeuMoDx that Qiagen doesn't already own • Status: Closed • Qiagen purchased 19.9% stake in 2018 and currently distributes the NeuMoDx 288 + NeuMoDx 96 testing platforms in Europe and other markets outside the US
Bruker	Canopy Biosciences	• Price: Undisclosed • Status: Closed • Addition of Canopy's gene editing, gene expression analysis and bioprocessing services expands Bruker's product line for targeted multi-omics and fluorescence-based imaging technologies
LabCorp	Franciscan Missionaries of Our Lady Health System	• Price: Undisclosed • Status: No closing date announced • LabCorp acquires FMOLH's clinical ambulatory lab business and will provide reference testing for all of the latter's facilities and clinics
Hologic	Acessa Health	• Price: $80 million in cash and contingency payments • Status: Closed • Acquisition of firm and its markets the Acessa ProVu laparoscopic system bolsters Hologic's position in gynecological surgery space and broaden its fibroid treatments portfolio

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FDA WATCH

Respiratory Panel Tests Flow from EUA Pipeline Ahead of Flu Season

The robust COVID-19 testing EUA pipeline has opened up a new opportunity for companies that produce multi-analyte panels capable of detecting not only the SARS-CoV-2 virus but other respiratory viral infections. And with the approach of flu season, half a dozen of these panel tests have reached the U.S. market with more to follow.

The New FDA Multi-analyte Testing Policy

As it customarily does, the FDA signaled its new policy of granting EUA to panel tests bundling SARS-CoV-2 with other respiratory viruses via informal guidance by posting a new Q&A to its website Questions & Answers for COVID-19 testing labs and test manufacturers. The new QA, which was posted on Sept. 9, notes "the overlap in signs and symptoms between SARS-CoV-2 and other respiratory

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FDA Watch, *from page 5*

viral infections, including influenza." Multi-analyte panels capable of detecting and sorting out different viruses "are useful when multiple respiratory pathogens are circulated at the same time, as is expected with the upcoming flu season."

The FDA also listed the factors it would consider in deciding whether to issue an EUA for such tests, including:

- The extent to which the test aids differential diagnosis;
- Whether the proposed use meets the requirements for the public health emergency declaration; and
- The approval or clearance status of the individual tests within the panel.

Multi-Analyte Respiratory Panel Laboratory Tests with EUA Clearance

As of Sept. 29, the FDA has awarded EUA to the following multi-analyte respiratory panel tests:

- QiaStat-Dx Respiratory SARS-CoV-2 Panel (Qiagen)
- BioFire COVID-19 Test (BioFire Defense)
- BioFire Respiratory Panel 2.1 (RP2.1) (BioFire Diagnostics)
- Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay (U.S. Centers for Disease Control and Prevention)
- Cobas SARS-CoV-2 & Influenza A/B Nucleic Acid Test for use on Cobas Liat System (Roche)
- Xpert Xpress SARS-CoV-2/Flu/RSV test (Cepheid)

Here are some of the other key FDA EUAs and approvals announced in September:

New FDA Emergency Use Authorizations (EUAs) & Approvals

Manufacturer(s)	Product
Clear Labs	EUA for Clear Dx SARS-CoV-2, first nanopore sequencing-based test for SARS-CoV-2 with EUA
Quadrant Biosciences	EUA for Clarifi COVID-19 Test Kit
KimForest Enterprise	EUA for SARS-CoV-2 Detection Kit v1
Assure Tech	EUA for Assure COVID-19 IgG/IgM Rapid Test Device, first antibody point of care assay to detect previous SARS-CoV-2 infection with EUA
Vela Diagnostics	EUA for ViroKey SARS-CoV-2 RT-PCR Test v2.0

Manufacturer(s)	Product
GK Pharmaceuticals Contract Manufacturing Operations (GK CMO)	EUA for GK Accu-Right SARS-CoV-2 RT-PCR Kit
Shenzhen New Industries Biomedical Engineering (SNIBE)	EUA for Maglumi 2019-nCoV IgM/IgG test
Accelerate Diagnostics	510(k) clearance for enhancements to Accelerate Pheno system
Hologic	EUA for Aptima SARS-CoV-2 assay
Abbott Laboratories	EUA for BinaxNow COVID-19 Ag Card, a SARS-CoV-2 antigen test that doesn't require an analyzer to read results
Color Genomics	EUA for Color COVID-19 Self-Swab Collection Kit
Thermo Fisher Scientific	Premarket approval for Oncomine Dx Target Test as companion diagnostic for pralsetinib (Gavreto) drug developed by Blueprint Medicines to identify RET fusions in metastatic non-small cell lung cancer patients
Roche	Expanded clearance for CINtec Plus Cytology test for use in patients with human papillomavirus
Roche	EUA for Cobas SARS-CoV-2 & Influenza A/B test
Roche	510(k) clearance for Cobas test for BK virus to run on Cobas 6800 and 8800 Systems
Roche	Clearance for Cobas HIV-1/HIV-2 Qualitative Test on Cobas 6800 and 8800 Systems
BioCheck	EUA for BioCheck serological SARS-CoV-2 IgM and IgG test kits
Verily Life Science	EUA for Verily COVID-19 RT-PCR Test
DiaSorin	Clearance for Simplexa Flu A/B and RSV Direct Gen II kit
BillionToOne	EUA for qSanger-COVID-19 sequencing-based SARS-CoV-2 test
Sugentech	EUA for SGTi-flex COVID-19 IgG serological test
Bioeksen R&D Technologies	EUA for Bio-Speedy Direct RT-qPCR SARS-CoV-2 test
Detectachem	EUA for MobileDetect Bio BCC19 Test Kit
Optolane Technologies	EUA for Kaira 2019-nCoV Detection Kit
Color Genomics	EUA for COVID-19 Test Unmonitored Collection Kit
Mammoth Biosciences	EUA for SARS-CoV-2 DETECTR Reagent Kit, a CRISPR-based RT-LAMP test
TBG Biotechnology	EUA for TBG SARS-CoV-2 IgG/IgM Rapid Test Kit
T2 Biosystems	EUA for T2SARS-CoV-2 panel
HelixBind	Breakthrough Device Designation for RaPID/BSI test for bloodstream infections associated with sepsis
Foundation Medicine	Clearance for s FoundationOne Liquid CDx, a multi-cancer comprehensive liquid-biopsy test, for multiple companion diagnostic indications including one for prostate cancer and three for lung cancer

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FDA Watch, *from page 7*

New CE Marks & Global Certifications

Notable European CE certifications announced during the period:

NEW CE MARKINGS IN EUROPE

Manufacturer(s)	Product
BGI Genomics	Two different multiplexed tests for SARS-CoV-2 and influenza A/B
DiaSorin Molecular	Simplexa COVID-19 Direct test
Cytek Biosciences	Cytek Northern Lights flow cytometer
Eurobio Scientific	EBX 042 FluCoSyn test
GenMark Diagnostics	ePlex Respiratory Pathogen Panel 2
ProciseDx	Procise IFX and Procise ADL tests measuring infliximab and adalimumab levels
Omega Diagnostics	Mologic's COVID-19 lateral flow antibody test to be marketed under the Omega Visitect brand
Novacyt	Winterplex PCR-based respiratory panel differentiating SARS-CoV-2 from common winter infections

Other international clearances announced during the period:

Manufacturer(s)	Country(ies)	Product(s)
Yourgene Health	Australia	Therapeutics Goods Association approval of Iona Nx NIPT workflow as a Class 3 medical device

Diagnostics Deals: National Grocery Firm Begins In-Store Sales of Saliva-Based COVID-19 Test Kits

With labs continuing to face supplies shortages, saliva-based COVID-19 test kits that eliminate the need for swabs, lab professionals and PPE during the sample collection process are growing in use. And the newly announced partnership between test maker Phosphorous and grocery firm Albertsons Companies is among the first to offer saliva tests via the mass retail channel.

Deal Details

Under the deal, Albertsons will offer Phosphorous' at-home SARS-CoV-2 saliva test kits at its in-store pharmacies across the country. The COVID-19 RT-qPCR Test can detect RNA from the virus in specimens that can be collected by patients at home using the DNA Genotek Oragene

Dx OGD-510 collection kit from OraSure Technologies, which received Emergency Use Authorization from the FDA in June.

The deal actually expands the original pilot Albertsons rolled out successfully in Houston, Austin and Boise to all of its markets. Albertsons operates stores in 34 U.S. states and the District of Columbia.

To obtain a test kit, customers must complete an online questionnaire for review by an Albertsons pharmacist. Once approved, customers either pick up the test or have it delivered, carry out the saliva sample collection process from home and send the sample to Phosphorus' lab in Secaucus, New Jersey. Customers can get test results by email or text within 72 hours and consult with Albertsons pharmacists if they have follow-up care questions. The kit costs $139.99 and Albertsons says that it isn't allowed to directly bill customers' insurers for those costs.

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Here's a summary of other key strategic diagnostic deals announced in September 2020:

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS

Partner 1	Partner(s) 2+	Deal Summary
Siemens Healthineers	US Centers for Disease Control and Prevention + Joint Research Centre of European Commission	• Objective: Develop international process for standardizing SARS-CoV-2 assays • Dynamic: Process will involve anchoring each type of SARS-CoV-2 protein to a neutralization antibody titer
Siemens Healthineers	Novartis Pharma	• Objective: Develop diagnostic tests for Novartis' therapeutic products • Dynamic: Initial effort will focus on creating a serum neurofilament light chain (NfL) immunoassay to support Novartis' MS and other neuroscience programs
Foundation Medicine	Takeda Pharmaceuticals USA	• Objective: Develop companion diagnostics for use with Takeda's lung cancer treatment products • Dynamic: Use FoundationOne CDx and FoundationOne Liquid CDx to identify patients eligible for mobocertinib or brigatinib (Takeda's Alunbrig)

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Diagnostics Deals, *from page 9*

Partner 1	Partner(s) 2+	Deal Summary
Thermo Fisher Precision Medicine Science Center	AstraZeneca + University of Nebraska Medical Center	• Objective: Develop new clinical protein biomarker discovery solutions • Dynamic: Conduct studies using standardized plasma protein profiling workflows, including Thermo Fisher's ultra-high throughput plasma protein profiling workflow, to discover biomarkers for a range of conditions
Todos Medical	Care GB Plus	• Objective: Develop and commercialize Todos Biochemical Infrared Analyses cancer diagnostic platform in Europe, Israel and Africa • Dynamic: Geographic expansion of earlier agreement which covered only Israel, under which firms will form a joint venture for tests, with Care GB owning 67% and Todos 33% of venture
Bio-Techne	Qiagen	• Objective: Development new exosome-based products and comarket exosome technology to biopharma companies • Dynamic: Exclusive partnership giving Qiagen a non-exclusive development license to Bio-Techne's exosome technology for development of companion diagnostics • After codevelopment, firms to also promote exosome technology to their respective global biopharma partners for 24 months ending in 2028, with the potential to extend
Cellex	Gauss	• Objective: Launch a SARS-CoV-2 antigen test for at-home and point-of-care use • Dynamic: Cellex is developing the test which will be integrated with a mobile phone app developed by Gauss to provide instructions on how to collect a nasal swab specimen and perform the test

Partner 1	Partner(s) 2+	Deal Summary
IncellDx	MD Biosciences	• Objective: Validate and launch IncellDx's COVID-19 cytokine storm panel • Dynamic: MD Biosciences to validate the test and being offer it through its CLIA-certified labs in the US and Europe • Agreement also covers receptor occupancy assays for CCR5-directed therapeutics, which are being evaluated as treatments for COVID-19
Foundation for Innovative New Diagnostics (FIND)	Africa Centres for Disease Control and Prevention	• Objective: Promote establishment of COVID-19 rapid diagnostic testing capacity across Africa • Dynamic: FIND has convened the Access to COVID-19 Tools Accelerator Diagnostics Pillar, of which Africa CDC is a member, to build technical capacity to allow African countries to implement rapid testing without delay
SkylineDx	Imperial College London + University of California San Diego School of Medicine	• Objective: Develop diagnostic test for early diagnosis of Kawasaki disease (KD) • Dynamic: Test, which will be based on 13 genes that form a gene signature in blood of children with KD, will be able to distinguish KD from other infectious and inflammatory diseases
Oncocyte	Guardian Research Network	• Objective: Improve precision medicine clinical trials from patient recruitment thru regulatory approval, starting with immuno-oncology • Dynamic: Leverage GRN's clinical trial enrollment and data science technology in combination with Oncocyte's molecular tests and pharma and companion diagnostic development services
BiomX	Boehringer Ingelheim	• Objective: Discover biomarkers associated with patient phenotypes in inflammatory bowel disease • Dynamic: BiomX to generate metagenomic data for gut microbiome samples from IBD patients using its XMarker biomarker discovery platform • Boehringer Ingelheim gets option to negotiate exclusive rights to biomarkers discovered

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Diagnostics Deals, *from page 11*

Partner 1	Partner(s) 2+	Deal Summary
SG Blocks	Clarity Diagnostics	• Objective: Establish CLIA-certified labs in the US • Dynamic: Joint venture, called Clarity Modular Lab Solutions, will construct labs using structures developed by SG Blocks with the latter to own 51% of the joint venture
Amoy Diagnostics	Haihe Pharmaceutical	• Objective: Codevelop companion diagnostic test for Japanese market • Dynamic: Test to be based on AmoyDx's PCR platform for use with Haihe's MET kinase inhibitor Glumetinib (SCC244), which targets c-MET exon14 skipping alterations in non-small cell lung cancer patients
Natera	Mass General Cancer Center of Massachusetts General Hospital	• Objective: Collaborate on early-stage breast cancer clinical trial of a molecularly targeted therapy • Dynamic: Investigator-initiated, multi-center, Phase II randomized trial, called LEADER, to evaluate Ribociclib (Novartis' Kisqali), a CDK4/6 inhibitor, for treatment of ER-positive breast cancer, using Natera's Signatera personalized liquid biopsy test to determine patient enrollment eligibility

DISTRIBUTION, SALES & MARKETING AGREEMENTS

Product Owner	Distributor	Deal Summary
Yourgene Health	Immuno-Biological Laboratories (IBL-America)	• Products: Yourgene's Elucigene DPYD chemotoxicity assay and other reproductive health tests • Territory: US • Non-exclusive
BioMérieux	Baxter International	• Products: BioMérieux's Nephroclear CCL14 diagnostic test, currently in development, for assessing risk of developing persistent sever acute kidney injury (AKI) once it gets regulatory approval • Territory: US, Europe • Exclusive

Product Owner	Distributor	Deal Summary
Capitainer	Speciality Diagnostix	• Products: Capitainer's qDBS dried blood spot sampling product • Territory: Europe, Australia, New Zealand
ArcDia International	Hain Lifescience	• Products: ArcDia's MariPOC point-of-care testing platform and related infectious diseases immunoassays • Territory: Germany, Austria, Switzerland, Belgium, Netherlands, Luxembourg • Exclusive
Universal Sequencing Technology	Golden Gateway Partners	• Products: UST's Transposase Enzyme Linked Long-read sequencing (TELL-Seq) kit • Territory: Australia • Exclusive

LICENSES

Licensor	Licensee	Deal Summary
ERS Genomics	Applied StemCell	Applied StemCell to commercialize CRISPR gene editing services and reagents
MeMed	DiaSorin	DiaSorin gets right to commercialize MeMed's BV test for distinguishing between bacterial and viral infections for use on its own Liaison analyzer platform

SUPPLY, SERVICE & TESTING AGREEMENTS

Supplier/ Servicer	Client/User	Deal Summary
Avacta Group	Abingdon Health	Abingdon to manufacture saliva-based rapid SARS-CoV-2 antigen test Avacta is developing with Cytiva
Pangea	Todos Medical	Todos to be preferred supplier of Pangea's COVID-19 testing products for contract tracing and will also integrate and tailor Pangea's technology into its service offerings in US, Canada, and Mexico to create "COVID bubbles" for employers, schools, sports leagues and other clients

Direct-To-Consumer: Walmart & Quest Provide Drone Delivery of At-Home COVID-19 Test Kits

The previous decade has seen the direct-to-consumer (DTC) diagnostics products business take quantum leaps forward thanks to collaborations between major lab companies and retail giants that enable shoppers to purchase tests and drugs and groceries at the same time. But like just about everything else, the COVID-19 pandemic has posed challenges to this business model by forcing shoppers to remain at home and receive contactless delivery. But now Walmart and Quest Diagnostics may just have come up with a high-tech solution: Deliver test kits by drone.

The Drone Delivery Deal

The arrangement among Quest, Walmart and drone services company DroneUp to provide drone delivery of SARS-CoV-2 home collection kits is, ironically enough, a pilot program being carried out as part of a broader initiative evaluating the potential role of drones in pandemic response and general healthcare delivery. The pilot will "examine how drones could deliver health care to patients who are unable to leave their home or live in remote locations," noted **Dan Haemmerle**, general manager of extended care at Quest, in a statement. We will take the learnings from this pilot and enhance the ways we deliver health care services."

During October, drones will deliver Quest SARS-CoV-2 home collection kits to patients living in single-family residences within a 1-mile radius of two designated Walmart Supercenters, one in North Las Vegas and the other in Cheektowaga, NY. The drones will land on the driveway, front sidewalk or backyard of the patient's home, depending on where there are cars and trees. After receiving the kits, patients will perform a self-administered nasal swab in the privacy of their home and send their sample back to Quest for testing using the included prepaid shipping label. They can then access test results on the Quest online portal or app. Both the kit and home delivery are provided free of charge, as long as patients meet the program criteria and CDC and state and local public health guidelines COVID-19 testing requirements.

Drones and DTC Diagnostics

Quest and Walmart have been working together to deliver DTC testing since the pandemic began with the former currently offering drive-through SARS-CoV-2 testing at 500 Walmart locations around the country.

Takeaway

Drone delivery isn't just a fad or one-time response to COVID-19. On the contrary, it may represent the next stage in the evolution of DTC collaboration between labs and retail. Like other major retailers, Walmart has to respond to moves from rival Amazon, which recently received U.S. Federal Aviation Administration to fly its Prime Air delivery drones. And even before the pandemic, the drone model has also been tried in the healthcare space. In 2019, CVS entered into a drone delivery of in-store products agreement with United Parcel Service.

■ Genomic Testing: Utilization Is Low & Geographically Inconsistent but Not Just Due to Payor Coverage, *from page 1*

be one size fits all. But the effectiveness of personalized medicine relies on utilization of genomic testing and other diagnostics to inform medical decision making. The tests are there. But they're new and, at least in the eyes of many insurers and other payors, unproven. The question, then, is whether genomic tests are being utilized and, if not, what can be done to promote greater utilization?

To answer these questions, the project researchers analyzed utilization and coverage of genomic testing in three clinical areas over a three-year period:

- Noninvasive prenatal testing (NIPT) for prenatal screening;
- Whole exome sequencing (WES) for rare and undiagnosed genetic diseases; and
- Comprehensive genomic profiling (CGP) of tumors in advanced cancer patients.

To analyze utilization and coverage patterns, they drew from four sources of aggregated data:

- Test and policy catalogs;
- U.S. census data;
- Payer claims data; and
- Plan membership data.

The 3 Key Findings

The report makes three key findings:

1. Geographic Inconsistencies in Utilization

Medically appropriate genomic testing is inconsistently utilized across U.S. states, the report finds. Examples of notable inconsistencies from 2019 annualized utilization data from California, Florida, Illinois and Texas:

- NIPT utilization was between 36 percent and 72 percent higher in Texas than in California, Illinois and Florida;
- WES utilization in California was 71 percent higher than in Florida and 65 percent higher than in Illinois; and
- CGP utilization was between 47 percent and 69 percent higher in Florida than it was in Texas, Illinois and California.

2. Geographic Inconsistencies in Payor Coverage

The report also finds that payor genomic testing coverage policies vary considerably among states and are inconsistent. NIPT had the highest average policy scores and relatively consistent coverage across the U.S. But

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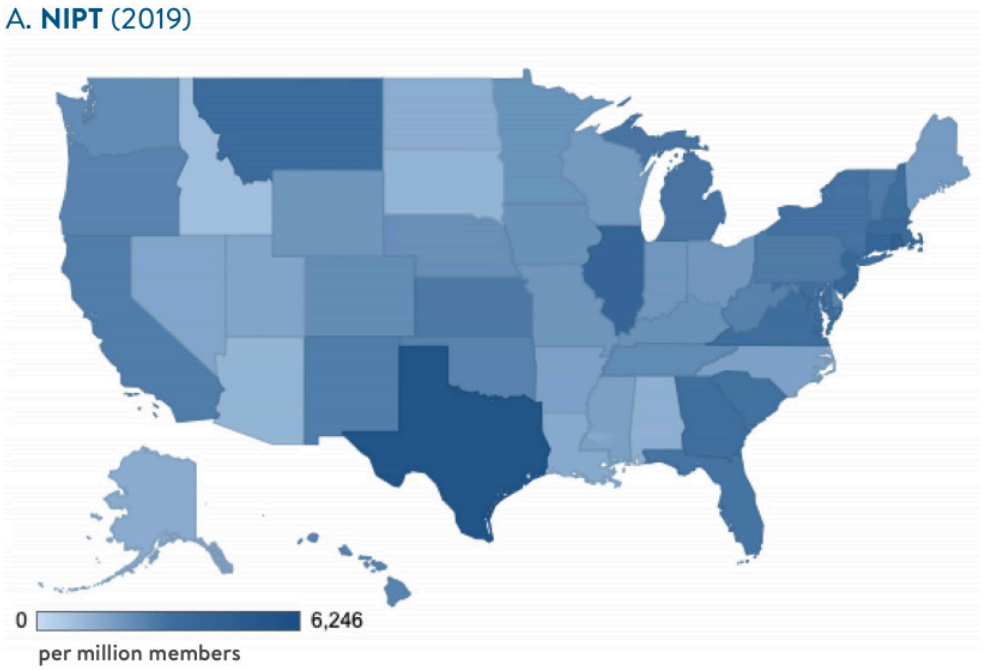
Genomic Testing: Utilization Is Low & Geographically Inconsistent but Not Just Due to Payor Coverage, *from page 15*

average policy scores for WES and CGP were lower and less consistent nationwide. Even so, coverage of all three tests has been growing over time, the report notes.

3. More Coverage Doesn't Necessarily Lead to More Utilization

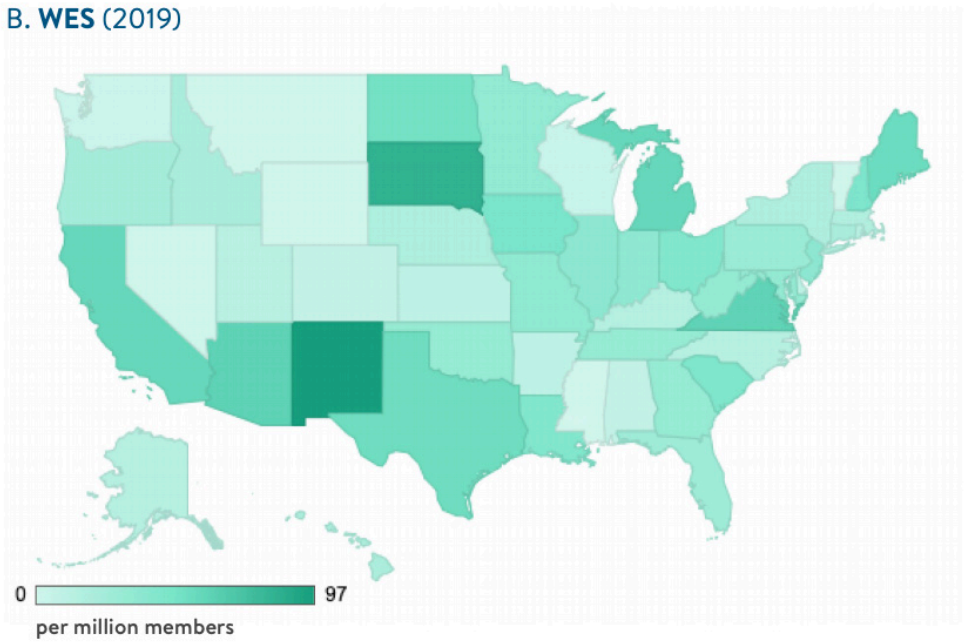
Perhaps surprisingly, the report finds that favorable genomic test coverage policies don't always correlate with higher utilization rates across states. Thus, in some of the states where coverage expanded, there were no correlating increases in utilization. In Illinois, New Jersey and Texas, genomic testing utilization increased but so did utilization in all other clinical areas. Some of the states with high coverage policy scores saw low utilization, e.g., Colorado for WES and Washington for NIPT and CGP. And in still other states, utilization was high even though the coverage score was low (e.g., New York and Connecticut for NIPT; and Ohio and California for CGP and WES).

Utilization of Noninvasive Prenatal Testing (NIPT)



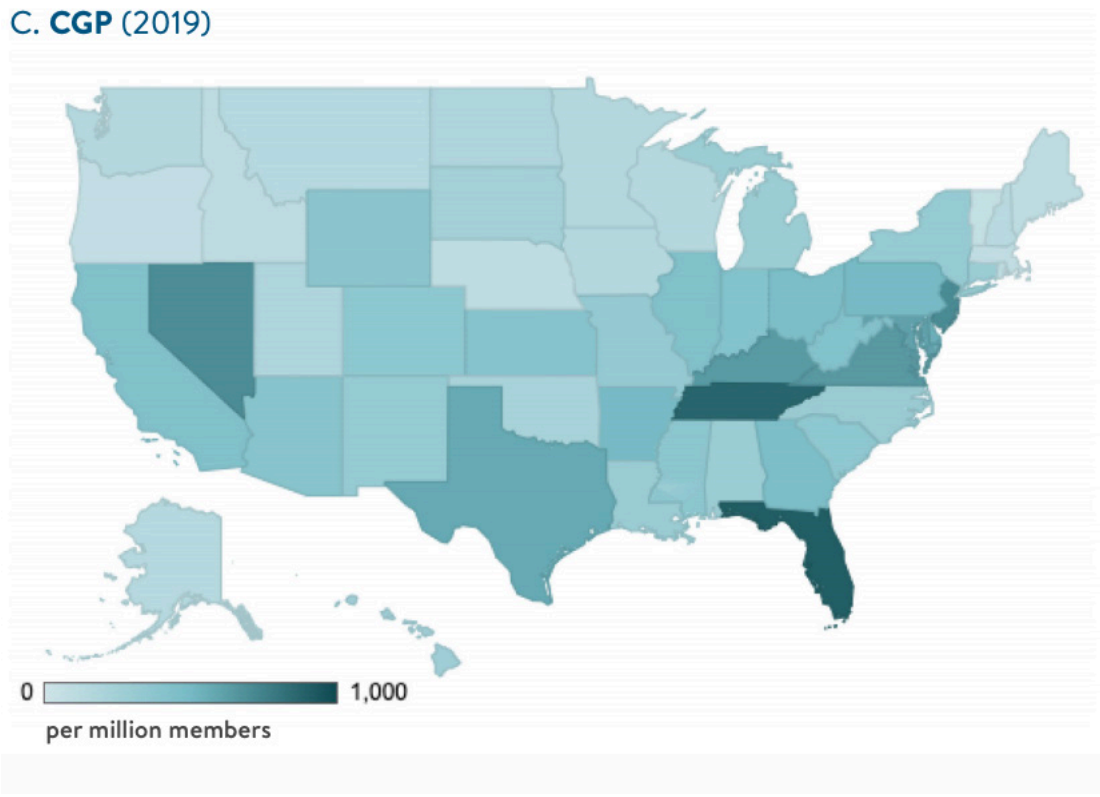
Source: PMC

Utilization of Whole Exome Sequencing (WES)



Source: PMC

Utilization of Comprehensive Genomic Profiling (CGP)



Source: PMC

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■ Genomic Testing: Utilization Is Low & Geographically Inconsistent but Not Just Due to Payor Coverage, *from page 17*

Takeaway

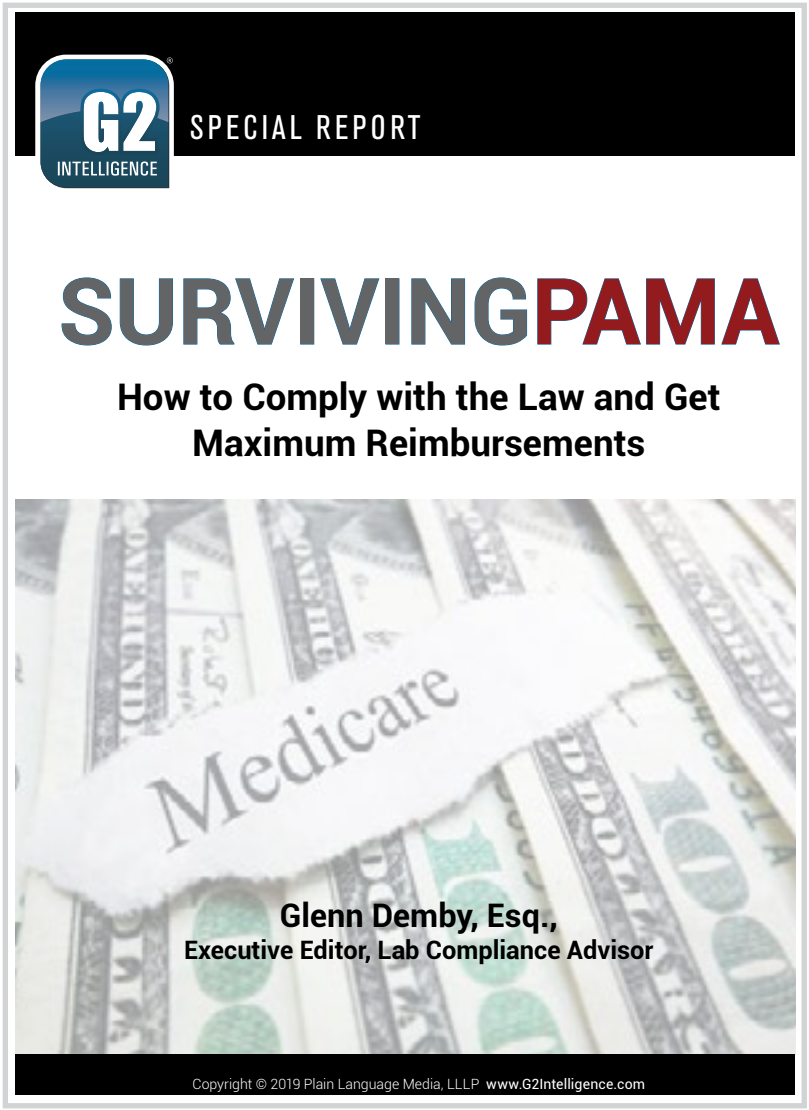
Utilization of genomic testing remains low and inconsistent across the country. Local payor coverage and reimbursement policies mirror that inconsistency and aggravate the problem; but they aren't the only reason it exists. The PMC report concludes that there are also other access barriers that may be stifling utilization of genomic testing, including:

- *Lack of awareness and education about genomics and testing technologies;*
- *Socioeconomic disparities; and*
- *Inadequate genomic testing system processes and practices.*

So, while persuading and standardizing the payors will be an important part of the solution, these other barriers will also have to be addressed to deliver on the promise of genomic testing and personalized medicine.

PAMA

Is Not Going Away Anytime Soon!



It is absolutely critical for every clinical lab to **understand the law** and know how to **comply with the law**.

This Special Report looks at what went wrong. More importantly, it focuses on **actual PAMA requirements** and gives you **practical, "how-to" help you need to comply with the Law** and position your lab to **get maximum reimbursements allowed by PAMA**.

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