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Market Trends: COVID-19 Fuels Massive & Sustainable Growth in Molecular Diagnostics

While it may be decimating demand for most lab tests, COVID-19 is driving incredible growth in molecular testing. The global market for molecular diagnostics will top $13 billion in 2020, about $5 billion more than last year. That's the eye-popping but not surprising finding of a new report from medical market research firm Kalorama Information.

Report Methodology

Kalorama's data reflect sales estimates and forecasts based on country- and state-reported test volumes, pricing data and revenues of IVD manufacturers. The worldwide totals

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Diagnostics Deals: 3M and MIT Team Up to Create Rapid, Scalable SARS-CoV-2 Antigen Test

Unlike reverse transcription-polymerase chain reaction (PCR) and blood-based serology antibody assays, antigen tests are relatively inexpensive to produce and generate results rapidly at the point of care. This combination of scalability and speed makes antigen testing a potential solution to the urgent need for high throughput SARS-CoV-2 testing. The problem is that development of antigen tests currently lags behind PCR and serology tests. But now a pair of powerhouses, one from the corporate and the other from the academic world, are setting out to close the gap and bring SARS-CoV-2 tests to market on a massive scale.

The 3M-MIT Collaboration

On July 14, 3M and the Massachusetts Institute of Technology

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include reagents and instruments and directly related sales. Estimates include revenue to IVD manufacturers but not lab revenues. Kalorama also excluded antibody sales.

The report considered not just reverse transcription polymerase chain reaction (PCR) molecular tests detecting RNA from the SARS-CoV-2 virus but also assays for HIV, hepatitis, cancer, inherited diseases and other non-COVID-19 diseases and conditions.

From $0 to $4.4 Billion in the Blink of an Eye

Molecular diagnostics was already a growth area before the pandemic. But Kalorama estimates that COVID-19 testing will add $4.4 billion to the mix, causing the total for all molecular tests sold for a clinical diagnostic purpose to exceed $13.4 billion this year. And to think, none of this COVID-19 testing revenue existed in 2019, or even the first two months of 2020. The surge began after Q1 in April, when worldwide cases began to spike. However, Kalorama also found that volume has been levelling off in recent months, citing the following factors:

- The "first wave" of the pandemic has passed in regions of Western Europe and Asia;
- Countries with growing case numbers have already ramped up testing capacity to maximum growth levels; and
- Test volume has been hindered by shortages of supplies, RNA extraction kits and PPE.

Is Growth a Fixture or a Flash in the Pan?

Kalorama expects strong growth in molecular diagnostics to continue at least into 2021, especially given current COVID-19 disease trends. COVID-19 testing revenues will likely be significant in the next few years, even when current crisis demands subside and COVID-19 tests become elements of panels for flu and other respiratory conditions.

More significantly, molecular diagnostics revenues will probably keep growing fast even without COVID-19 tests, fueled by the expected surge of "make-up" healthcare visits and procedures that were put on hold during the pandemic. "If molecular resources normally dedicated to other tests are diverted to COVID-19, the overall market for molecular diagnostics will continue to grow," reports Kalorama, noting that many COVID-19 test makers produce tests for other infectious diseases such as HIV and Zika.

Takeaway

COVID-19 testing added jet fuel to a market that was already enjoying rapid growth before the pandemic. Although the powerful surge

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is unprecedented and ultimately unsustainable, COVID-19 testing will continue to generate significant revenues for a few more years. But molecular test makers and labs will continue to make money at accelerated rates as a result of make-up testing and, in the long term, as a result of what the pandemic has done to raise awareness of PCR and other forms of molecular tests.

Emerging Tests: FDA Offers New Guidance on Validating SARS-CoV-2 Tests in "Non-Laboratory" Settings

SARS-CoV-2 testing in homes, workplaces, airports, schools, sports venues and other non-traditional diagnostic settings is likely to play an increasingly important role in the months ahead. The FDA has indicated that it's "supportive of testing" in non-laboratory settings, "provided there is data and science to support consumer safety and test accuracy." And on July 28, the agency issued a new guidance template to help test makers validate these non-laboratory products.

The Template

The Template for Manufacturers of Molecular and Antigen Diagnostic COVID-19 Tests for Non-Laboratory Use makes recommendations on safety and performance and outlines strategies for validating assays and associated smartphone apps. The template applies only to molecular and antigen testing of respiratory specimens or saliva and not blood, stool or other non-respiratory samples. Nor does the template cover at-home collection kits.

The 8 Recommendations

Key recommendations listed in the template:

1. The comparator sample for non-lab test evaluations should be a nasopharyngeal swab collected by a healthcare provider "within a reasonable time frame" from when the sample was obtained;
2. Samples should be assessed with a robust molecular SARS-CoV-2 test that has received Emergency Use Authorization (EUA);
3. To ensure usability by lay persons, non-prescription over-the counter (OTC) tests should be run by at least 100 participants, which may include having 50 participants testing themselves and 50 participants testing somebody else;
4. Prescription tests usability studies should be run by 30 participants, 15 of whom should be parents or guardians testing their kids;

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Emerging Tests: FDA Offers New Guidance on Validating SARS-CoV-2 Tests in "Non-Laboratory" Settings, *from page 3*

5. Study participants should represent different ages and education levels and include Spanish speakers provided instructions in Spanish;
6. There should be a separate clinical evaluation done on at least 150 people, both the symptomatic and asymptomatic, that runs until 30 positives are obtained with the goal of at least 10 positives among the asymptomatic participants;
7. OTC tests should have a positive percent agreement (PPA) of 90 percent for asymptomatic and symptomatic people, and a negative percent agreement (NPA) of 99 percent; and
8. Prescription tests should have a PPA bar of 80 percent.

Takeaway

The last week of July was a busy one for the FDA. In addition to the new template for non-lab tests, the agency updated its previous guidance templates on validating pooled, multi-analyte and point-of-care testing.

New FDA Guidance for SARS-CoV-2 Molecular Test Makers & Labs

Testing Type	Key Revisions
Pooling	*Recommendations for validating pools of samples from aliquots of transport media and pooled patient swabs *PPA of 85 percent between pooled tests and individual test results *Plan for monitoring local positivity rates should be provided
Multi-analyte	FDA clarifies that in determining whether to authorize a test it considers whether the inclusion of other targets will aid in differential diagnosis of SARS-CoV-2, whether the other targets are already authorized and how the panel fits into current public health recommendations, etc.
Point-of-care	*EUA request should include data demonstrating that non-lab personnel can perform test accurately in intended use environment *EUA request should also include data demonstrating the robustness of the test device for near patient testing *Tests on system that's CLIA waived require assay performance data only *PPA and NPA should be 95 percent (although PPA of 80 percent may be okay for some intended uses)

FDA WATCH

Agency Green Lights First SARS-CoV-2 Tests for Sample Pooling

Revising an Emergency Use Authorization (EUA) to permit a new clinical use is usually pretty routine stuff. But the expanded EUA the FDA announced on July 18 was both unprecedented and significant because it was the first time the agency has given the green light for use of a previously cleared test on pooled samples.

The Quest SARS-CoV-2 Test

The Sir Edmund Hillary of the sample poolers is Quest Diagnostics' SARS-CoV-2 RNA test, which initially received EUA back in March. The reissued EUA allow for use of the test with pooled upper respiratory specimens in sample pools comprised of four individuals. "The new update allows Quest to test 3,600 more tests per day," noted **Timothy Stenzel**, director of the Office of In Vitro Diagnostics and Radiological Health at FDA's Center for Devices and Radiological Health during a recent agency "town hall" briefing, "and if you add pooling on top of that. . . they can substantially increase the throughput."

Use of pooling enables testing labs to get the most out of testing resources and overcome supply shortages. But there's a tradeoff: Because pooling dilutes the nucleic acids produced by the SARS-CoV-2 virus, it creates the risk of false negatives. To secure the EUA expansion for the SARS-CoV-2 RNA test, Quest provided the FDA clinical data showing that none of a total 3,091 specimens from a population with a prevalence rate of 1 to 10 percent would have come back falsely negative had the specimens been pooled. Quest began immediately to perform pooled sampling testing with the assay starting with its laboratories in Marlborough, MA, and Chantilly, VA.

LabCorp Gets OK for Pooling & Asymptomatic Screening

Less than a week later, the FDA announced that LabCorp's COVID-19 RT-PCR Test had received the second expanded EUA for pooled SARS-CoV-2 testing. The LabCorp test is authorized for human specimen collection at home using the Pixel by LabCorp or other home sample collection kits authorized for use with LabCorp's test, or by a healthcare provider. However, only samples collected by healthcare providers may be pooled using the test, the FDA noted. The expanded EUA also allows the test to be used for testing the broad population under the FDA's new asymptomatic screening guidance, making it the first SARS-CoV-2 test to gain that distinction.

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FDA Watch, *from page 5*

Here are some of the other key FDA EUAs and clearances announced in July:

New FDA Emergency Use Authorizations (EUAs) & Approvals

Manufacturer(s)	Product
Eli Lilly and Company	EUA for Lilly SARS-CoV-2 Assay
Sandia National Laboratories	EUA for SNL-NM 2019 nCoV Real-Time RT-PCR Diagnostic Assay
Xiamen Biotime Biotechnology	EUA for Biotime SARS-CoV-2 IgG/IgM Rapid Qualitative Test, serology assay detecting and IgG and IgM antibodies
LabCorp	Reissued EUA for COVID-19 RT-PCR Test for testing asymptomatic patients and pooled sample testing
CoWin Biotech	EUA for Novel Coronavirus Fast Nucleic Acid Detection Kit run on Thermo Fisher's Applied Biosystems 7500 RT-PCR system
Helix OpCo	EUA for Helix COVID-19 Test detecting SARS-CoV-2 nucleocapsid, ORF1ab and spike protein genes
Thermo Fisher Scientific	Clearance for ImmunoCAP Specific IgE alpha-Gal Allergen Component blood test detecting sensitization to alpha-gal carbohydrate in red meat and assessing risk for an anaphylactic reaction
DiaCarta	EUA for QuantiVirus SARS-CoV-2 Multiplex Test Kit
Becton Dickinson	Premarket approval supplement for expanded BD Onclarity HPV Assay
Becton Dickinson	EUA for SARS-CoV-2 antigen test
Paige	510(k) clearance for use of FullFocus digital pathology image viewer with Philips Ultra Fast scanner for primary diagnosis
Access Genetics	EUA for OraRisk COVID-19 RT-PCR test
Megna Health	EUA for Rapid COVID-19 IgM/IgG Combo Test Kit (serology)
Luminex	EUA for xMap SARS-CoV-2 Multi-Antigen IgG Assay
Boston Heart Diagnostics	EUA for Boston Heart COVID-19 RT-PCR Test
Quest Diagnostics	EUA for 3 coronavirus assays: *PF SARS-CoV-2 Assay performed with Hologic's Panther Fusion SARS-CoV-2 RT-PCR-based test *RC SARS-CoV-2 Assay performed with Roche automated Cobas SARS-CoV-2 RT-PCR test *HA SARS-CoV-2 Assay
KogeneBiotech	EUA for PowerChek 2019-nCoV Real-time PCR Kit
Trax Management	EUA for PhoenixDx SARS-CoV-2 Multiplex
Beijing Wantai Biological Pharmacy	EUA for SARS-CoV-2 Ab Rapid Test lateral flow serology assay
Diazyme Laboratories	EUA for Diazyme DZ-Lite SARS-CoV-2 IgG antibody test

Manufacturer(s)	Product
BioSewoom	EUA for Real-Q 2019-nCoV Detection Kit
Enzo Life Sciences	EUA for Ampiprobe SARS-CoV-2 Test System
Access Bio	EUA for CareStart COVID-19 MDx RT-PCR test
Gene By Gene	EUA for RT PCR-based SARS-CoV-2 Detection Test
Saladax Biomedical	*De novo* clearance for MyCare Psychiatry Clozapine Assay rapid blood test for clozapine levels in psychiatric patients
Assure Tech	EUA for Assure COVID-19 IgG/IgM Rapid Test Device
US Centers for Disease Control and Prevention	EUA for Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay real-time RT-PCR test for simultaneous detection and differentiation of SARS-CoV-2, influenza A and influenza B
Centogene	EUA for PCR-based SARS-CoV-2 test
InBios International	EUA for SCoV-2 Detect IgM ELISA kit (serological)

New CE Marks & Global Certifications

Notable European CE certifications announced during the period:

NEW CE MARKINGS IN EUROPE

Manufacturer(s)	Product(s)
NowDiagnostics	AdexusDx COVID-19 serology antibody test for SARS-CoV-2
Bruker	FluoroType SARS-CoV-2 plus assay detecting two genes of SARS-CoV-2 genome
Devyser	Next-generation sequencing-based hereditary breast and ovarian cancer assay
PerkinElmer	Dry blood spot-based test for detecting SARS-CoV-2 IgG antibodies run on firm's GSP/Delfia platform
NeuMoDx Molecular	NeuMoDx HPV Assay molecular test for high-risk human papillomavirus types
BioMérieux	BioFire Respiratory Panel 2.1 plus for SARS-CoV-2 and other respiratory infections
Dante Labs	Immensa software for interpretating whole-genome sequencing data
Vela Diagnostics	Automated version of ViroKey SARS-CoV-2 RT-PCR Test
Advanced Biological Laboratories	UltraGene Combo2Screen SARS-CoV-2 qPCR assay
DiaSorin Molecular	Simplexa Flu A/B & RSV Direct Gen II assay for influenza and respiratory syncytial virus (RSV) run on firm's Liaison MDX real-time PCR instrument
Asuragen	AmplideX SMA Plus Kit test for spinal muscular atrophy
KDx Diagnostics	URO17 Bladder Cancer Recurrence urine test for bladder cancer
ContextVision	Inify Prostate Screening digital pathology product

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FDA Watch, *from page 7*

Manufacturer(s)	Product
Roche	uPath PD-L1 (SP263) automated digital pathology algorithm for non-small cell lung cancer
PathoFinder	RealAccurate Quadruplex SARS-CoV-2 PCR kit

Other international clearances announced during the period:

Manufacturer(s)	Country(ies)	Product(s)
DiaCarta	Mexico	Mexico Ministry of Health approval for QuantiVirus SARS-CoV-2 test
Sysmex	Japan	Ministry of Health, Labour, and Welfare approval for Automated Hematology Analyzer XN-31

Inside the Lab Industry: Humana, LabCorp, Quest and Walmart Partner on At-Home & Drive-Thru COVID-19 Testing

Humana is teaming up with the country's biggest retailer and two biggest testing labs to make it easier for members to get COVID-19 testing in non-traditional diagnostics settings. First, the national health insurer will pay for certain members who want to access at-home COVID-19 tests from LabCorp. It also announced that it's partnering with Walmart and Quest Diagnostics to offer COVID-19 testing at Walmart drive-thru pharmacies.

The Coverage Arrangements

Eligibility for the at-home and drive-thru tests is limited to members with Medicare Advantage, Medicare supplement, Medicaid and employer plans. Members who have only Medicare prescription-drug plan coverage, stand-alone vision or dental coverage, or Tricare don't qualify for the program.

Of course, Humana will also waive the usual copays and cost-sharing for eligible members receiving the tests. It has no choice in the matter. That's because the *Families First Coronavirus Response Act* (FFCRA) adopted in March requires health insurers to pay for medically COVID-19 tests at no cost to members. On April 11, CMS issued guidance clarifying that the ban on cost sharing covers at-home tests, as long as those tests are ordered by a healthcare provider who considers those tests medically appropriate for the patient.

How the Arrangement Will Work

Humana's game plan is to give members with COVID-19 symptoms or who've been exposed to COVID-19, e.g., via recent contact with a person confirmed as having the virus, the option of receiving an at-home test or drive-thru testing after they use the risk-assessment tool posted on the insurer's website.

If members opt for at-home testing, LabCorp will mail them an at-home test kit within one business day. The expectation is that members will generally receive their kits within one to two days of requesting the test, according to a Humana spokesman.

Members who opt for drive-thru testing currently will be able to go to 65 Walmart locations around the country. But Humana and Walmart are working to expand that to include 500 test sites by the end of the summer, the spokesman said.

M&A Report: Surging Demand for COVID-19 Testing Forces Thermo Fisher to Raise Its Offer for Qiagen

Back in March, Thermo Fisher Scientific announced that it had agreed to acquire Qiagen for $11.5 billion. At the time, the €39 (roughly $46) per share representing a premium of 23 percent over the March 2 closing price of Qiagen's common stock on March 2, seemed like a fair price. But then came the pandemic and the surge in demand for Qiagen's products for use in COVID-19 testing, which made €39 per share feel like chump change.

Qiagen Shareholders Demand a New Deal

Qiagen shareholders were quick to notice the disconnect between the tender price and current value of the molecular diagnostics company and accused the Qiagen board of failing to incorporate the impact of COVID-19 into the company's standalone value. "The Company's products have become increasingly important to governments and healthcare institutions as they seek to mitigate the risk of future pathogens and protect their citizens and economies," wrote Davidson Kempner in a letter. The institutional investor, which holds a 3% stake in Qiagen, called Thermo Fisher's offer price "inadequate," noting that "the deal has become even more attractive" since it was first announced and predicting that Qiagen 2020 earnings would increase 67%, as opposed to the 3.4% annual organic growth the company has averaged over the past decade.

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M&A Report: Invitae-ArcherDX Merger to Create Precision Oncology Powerhouse, *from page 9*

The New Acquisition Terms

The firms apparently took notice. On July 13, less than a week after the Davidson Kempner letter was published, Thermo Fisher and Qiagen unveiled an amended agreement "to reflect the fair value of the business given the current environment." Key terms:

- Offer price increased to €43 ($49) per share, which raises the premium to 35%;
- Minimum acceptance threshold of Qiagen's issued and outstanding share capital at the end of the acceptance period reduced from 75% to 66.67%; and
- $95 million expense reimbursement to Thermo Fisher if minimum acceptance threshold isn't met.

Following the announcement, Qiagen's supervisory and managing boards reaffirmed their unanimous support for and recommendation that shareholders accept the offer and tender their shares by the end of the acceptance period on August 10. Thermo Fisher is reportedly still expecting the deal to close in the first half of 2021.

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

MERGERS, ACQUISITIONS & ASSET SALES

Acquiring Company	Target(s)	Deal Summary
Grifols	Bloodbuy	• Price: Undisclosed • Status: Closed • Grifols acquires 10% stake in firm offering cloud-based marketplace for buying and selling of blood components
Curi Bio	Dana Solutions,	• Price: Undisclosed • Status: Closed • Acquisition of Silicon Valley developer of AI technologies for *in vitro* cell-based assays for drug discovery
Eurobio Scientific	Tecomedical	• Price: Undisclosed all-cash deal • Status: Closed • Acquisition of Swiss-based IVD test developer and distributor bolsters Eurobio's position in European market

Acquiring Company	Target(s)	Deal Summary
Illumina	Enancio	• Price: Undisclosed • Status: Closed • Acquisition of French genomic-specific compression software startup follows last month's purchase of BlueBee, a Netherlands-based bioinformatics firm
Predictive Oncology	Quantitative Medicine	• Price: $1.8 million • Status: Closed • Predictive to integrate drug-response and genomic profiles databases of its Helomics subsidiary with QM's machine-learning platform to develop new anti-cancer therapies
OncoDNA	IntegraGen	• Price: $16.4 million tender offer to purchase IntegraGen at $2.55 per share, premium of over 36% over last closing price of IntegraGen shares on Euronext Growth market of Euronext Paris • Status: Offer to open in Q3, subject to regulatory approval • Firms plan to combine IntegraGen's DNA sequencing services and bioinformatics tools with OncoDNA's oncology lab tests
LGC	Native Antigen Company	• Price: Undisclosed • Status: Closed • Acquisition of infectious-disease antigen and antibody supplier enables LGC to expand its portfolio of reagents
Quest Diagnostics	Mid America Clinical Laboratories	• Price: Undisclosed all-cash deal • Status: Expected to close in Q3 • Quest to acquire joint venture interests of its partner and run MACL itself • Quest to also sign long-term service agreement to provide hospital lab services to 30 hospital labs associated with MACL

Diagnostics Deals: 3M and MIT Team Up to Create Rapid, Scalable SARS-CoV-2 Antigen Test, *from page 1*

(MIT) announced that they are developing a rapid SARS-CoV-2 antigen test. The collaboration combines an MIT research team which specializes in creating and developing molecular technologies to boost performance of rapid cellulose-based protein tests with a 3M team led by scientists, manufacturers and regulatory experts from the company's corporate research laboratories and healthcare business group.

And there's a third partner, namely, the US National Institute of Health (NIH), which has provided initial funding of $500,000 under its new Rapid Acceleration of Diagnostics Tech (RADx) program to support "aggressively-paced COVID-19 diagnostics." The researchers will qualify for additional RADx funding if they can demonstrate the test's feasibility and commercialization potential after a four-week research period.

The Test

The 3M-MIT SARS-CoV-2 antigen test is designed to use a paper-based device to deliver test results within minutes at the point of care. When and if the test is validated, the researcher believe that it can be scaled to produce millions of units per day.

The Upside

"Antigen tests are important in the overall response against COVID-19 as they can generally be produced at a lower cost than PCR tests," according to FDA Commissioner **Stephen Hahn**. "And once multiple manufacturers enter the market, antigen tests can potentially scale to test millions of Americans per day due to their simpler design, helping our country better identify infection rates closer to real time."

The downside of antigen tests is that they're less sensitive than PCR assays, which makes them prone to false negatives. Accordingly, patients who test negative may need to have confirmatory PCR tests. But while PCR testing may be the gold standard for COVID-19 testing accuracy, it's not a high-throughput modality. In spite of its accuracy limitations, antigen testing may have to be relied on to meet the unprecedented demand for testing, especially for applications like screening health care workers and other high-risk groups and triaging patients during peak outbreak periods the way rapid influenza diagnostic tests are used during a bad flu season.

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

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS

Partner 1	Partner(s) 2+	Deal Summary
3M	Massachusetts Institute of Technology	• Objective: Developing rapid antigen test for SARS-CoV-2 • Dynamic: Viral antigen test would provide test results within minutes using a paper-based device at the point of care and be scaled to produce millions of units per day
Centogene	Molecular Health	• Objective: Develop new orphan drugs, starting with epilepsy • Dynamic: Carry out project called Real-life data and Innovative Bioinformatic Algorithms (RIBA) combining Centogene's real-life data sets in rare diseases with Molecular Health's expertise in big data, AI and computational algorithms
MP Biomedicals Asia Pacific	Singapore's Agency for Science, Technology and Research (A*STAR)	• Objective: Develop point-of-care antibody test for SARS-CoV-2 • Dynamic: Test has provisional regulatory authorization in Singapore regulators and is being distributed in Europe, Africa and South America with plans to seek EUA from FDA
Ultivue	OracleBio	• Objective: Offer pharmaceutical companies end-to-end workflow for tissue-based biomarker analysis • Dynamic: Firms to combine respective technologies for tissue staining and histopathology image analysis
BostonGene	NEC	• Objective: Analyze molecular profiles and tumor microenvironments of cancer patients in NEC's clinical trials to improve cancer treatment response • Dynamic: BostonGene to perform integrated genomic and transcriptomic next-generation sequencing on tumors of select patients across different cancer types and disease stages and analyze tumor microenvironment activity

Continued on page 14

Diagnostics Deals, *from page 13*

Partner 1	Partner(s) 2+	Deal Summary
Saga Diagnostics	SensID	• Objective: Develop control reagents for cancer mutation detection • Dynamic: Use use SensID's controls with Saga's digital PCR-based Sagasafe technology for detecting and quantifying ctDNA in cancer patients at ultra-low allelic frequencies
Microba	Synlab	• Objective: Launch MyBiome gut microbiome test in Europe and Latin America • Dynamic: Test measures bacterial species in gut microbiome and calculates their metabolic potential in relation to healthy reference ranges
Helix	San Diego County (California)	• Objective: Provide COVID-19 molecular diagnostics tests • Dynamic: Provide up to 2,000 of Helix's RT-qPCR assays per day out of Helix's San Diego lab
Thermo Fisher Scientific	First Genetics	• Objective: Commercialize NGS-based diagnostics in Russia • Dynamic: First Genetics, a Russian manufacturer, to market its IVD assays and F-Genetics NGS System, which is based on Thermo Fisher's Ion GeneStudio S5 sequencer, to Russian labs for reproductive health and cancer testing
Thermo Fisher Scientific	Chugai Pharmaceutical (part of Roche group)	• Objective: Develop CDx to identify ROS1-positive non-small cell lung cancer patients who may be eligible for treatment with entrectinib (Genentech's Rozlytrek, marketed in Japan by Chugai) • Dynamic: Thermo Fisher to also seek Ministry of Health, Labor, and Welfare of Japan approval to expand use of Oncomine Dx Target test in Japan

Partner 1	Partner(s) 2+	Deal Summary
Twist Bioscience	Takeda Pharmaceutical Company	• Objective: Develop new antibodies for oncology, rare disease, neuroscience and gastroenterology therapies • Dynamic: Twist to give Takeda access to its phage display libraries for use in discovery, validation and optimization of antibodies needed to develop new biologics in exchange for annual technology licensing fees, milestones and royalties for all compounds discovered from Twist libraries
Smiths Detection	Attomarker	• Objective: Develop and manufacture SARS-CoV-2 antibody testing device • Dynamic: Create miniaturized version of Attomaker Triple Antibody Test that works with smartphones to enable point-of-care and at-home testing
Guardant Health	Janssen Biotech	• Objective: Seek regulatory approval for and commercialize Guardant360 assay as CDx for amivantamab, Janssen's investigational EGFR-MET bispecific antibody for treating non-small cell lung cancer • Dynamic: Agreement covers US, Canada, Japan and Europe
Myriad Genetics	OptraHealth	• Objective: Develop chatbot named Gene to offer patients hereditary cancer information • Dynamic: Gene to fuse OptraHealth's GeneFax AI platform with Myriad's online hereditary cancer quiz
Genomics England	Amazon Web Services + Lifebit	• Objective: Create platform for researching COVID-19 data and analytics • Dynamic: Include data from Genomics England's research partnership with the Genetics of Mortality in Critical Care (GenOMICC) consortium, the NHS, and Illumina to sequence genomes from up to 35,000 SARS-CoV-2 patients

Continued on page 16

Diagnostics Deals, *from page 15*

Partner 1	Partner(s) 2+	Deal Summary
Proscia	Royal Philips	• Objective: "Advance an open ecosystem" to accelerate and scale adoption of digital pathology by labs • Dynamic: Integrate Philips' image format with Proscia's digital pathology platform
Pressure Biosciences (PBI)	Leica Microsystems (part of Danaher)	• Objective: Globally comarket mass spectrometry sample preparation platform • Dynamic: Platform combines Leica's laser microdissection (LMD) technology for precise cutting of small biopsy samples, and PBI's pressure cycling technology (PCT), for protein extraction and digestion from samples for mass spec analysis
Burning Rock Biotech	CStone Pharmaceuticals	• Objective: Co-develop and commercialize companion diagnostics for Blueprint Medicines' pralsetinib in China • Dynamic: Firms to promote standardization of RET gene testing in China

DISTRIBUTION, SALES & MARKETING AGREEMENTS

Product Owner	Distributor	Deal Summary
Oncocyte	ProGenetics	• Products: Oncocyte's DetermaRx test to identify patients at high risk for lung cancer recurrence who may benefit from adjuvant chemotherapy after tumor removal surgery • Territory: Israel
Menarini Silicon Biosystems	OpGen	• Products: Menarini's Cellsearch Circulating Endothelial Cell (CEC) Kit • Territory: North America
3D Medicines	Todos Medical	• Products: 3D Medicines' qPCR test kits and SARS-CoV-2 test • Territory: US • Todos gets exclusive right to seek FDA Emergency Use Authorization for test

LICENSES

Licensor	Licensee	Deal Summary
Massachusetts Institute of Technology	PathSensors	Expands current exclusive license to CANARY pathogen detection technology to include clinical applications starting with SARS-CoV-2
Massachusetts General Hospital	ProterixBio	ProterixBio licenses ELISA-based serology test measuring antibodies that bind to receptor binding domain of SARS-CoV-2 spike protein

SUPPLY, SERVICE & TESTING AGREEMENTS

Supplier/Servicer	Client/User	Deal Summary
BioReference Laboratories (Opko Health subsidiary)	US Centers for Disease Control and Prevention	Indefinite Delivery Indefinite Quantity (IDIQ) contract to provide antibody testing for national SARS-CoV-2serological survey
Quidel	US Department of Health and Human Services	HHS to purchase 2,000 Sofia and Sofia 2 instruments and 750,000 Sofia SARS Antigen FIA tests to detect SARS-CoV-2 in nursing homes

PAMA

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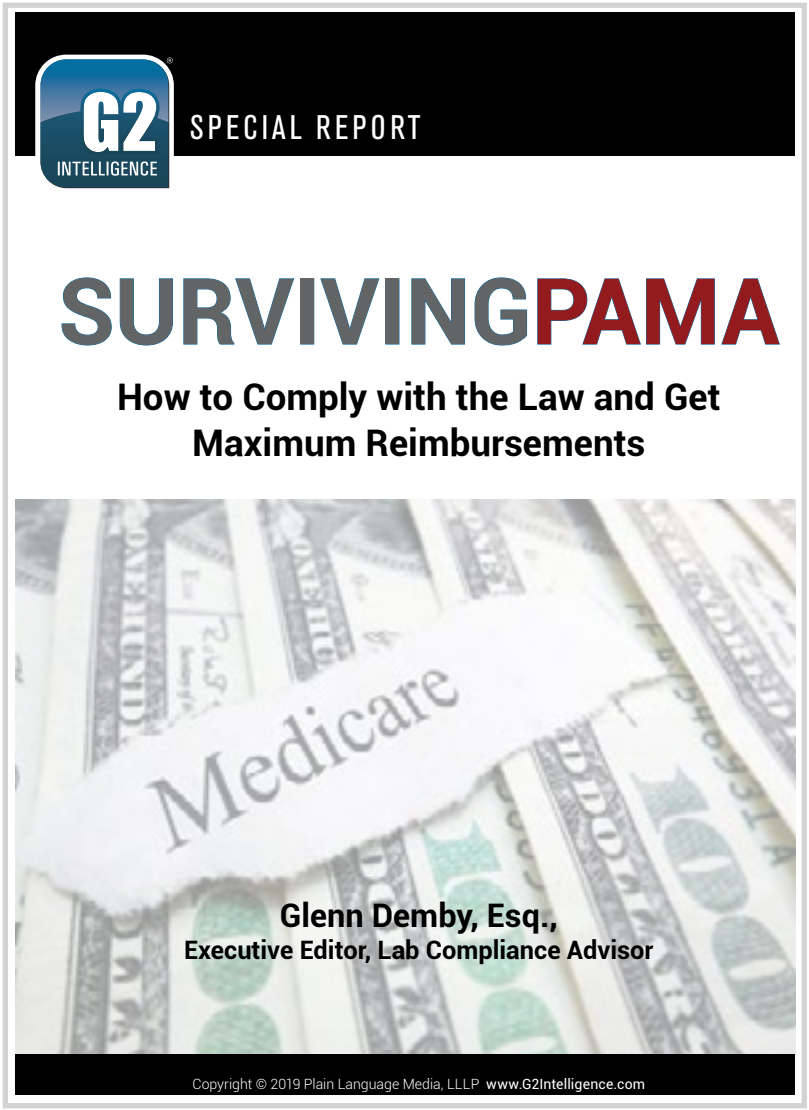

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