G2 INTELLIGENCE
A DIVISION OF PLAIN LANGUAGE MEDIA

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LABORATORY INDUSTRY REPORT™

Vol. 21, Iss. 2
February 2021

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G2Intelligence.com

Special Report: A New Administration Takes a Totally Different Approach to COVID-19 Testing

Fair or unfair, the general perception has been that the White House has been less than fully supportive of COVID-19 testing efforts during the pandemic. On Jan. 21, his first full day in office, President Biden released his plan to deal with the COVID-19 crisis. While vaccination takes center stage, the National Strategy for the COVID-19 Response and Pandemic Preparedness (National Strategy) emphasizes the importance of scaling and expanding testing by doing something the previous administration refused, namely, creating a

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DX Deals: Global Collaboration Seeks to Develop Game-Changing Handheld COVID-19 Breathalyzer Test

A handheld, easy-to-use breathalyzer device capable of accurately detecting COVID-19 at the point of care would represent a breakthrough in the effort to contain the spread of the virus. That vision may now be closer to reality thanks to a new international collaboration to test the idea's viability. Here's a look at the deal and its potential significance.

A New COVID-19 Testing Modality

Rapid and accurate point-of-care testing performed on a mass basis, including both the symptomatic and asymptomatic, is crucial to containing coronavirus spread. However, only a few of the COVID-19 diagnostic tests that have hit the U.S. market since the pandemic began have received regulatory approval for testing people who are asymptomatic.

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centralized federal agency to "oversee implementation of a clear, unified approach to testing."

The 7 Objectives

The National Strategy is organized around seven objectives:

- Restoring the trust of the American people;
- Mounting a safe, effective, and comprehensive vaccination campaign;
- Mitigating spread of the virus through the establishment of clear public health standards and expansion of masking, testing, data collection and analysis, treatments and the health care workforce;
- More extensive use of federal government control over industry under the *Defense Production Act* (DPA) to promote vaccination and testing;
- Safely reopening schools, businesses and travel;
- Protect those most at risk, including across racial, ethnic and rural/urban lines; and
- Restoring U.S. global leadership globally and advancing preparedness for future threats.

While the goals are pretty much what you'd expect, the key policy change is the establishment of a central COVID-19 Response Office responsible for coordinating pandemic response across all federal departments and agencies. To monitor outcomes, the National Strategy also calls for creation of publicly accessible performance dashboards to establish a data-driven, evidence-based approach to evaluate progress in the fight against COVID-19. Both of these initiatives are things that leading lab, hospital and other provider industry associations asked the previous White House and its COVID-19 Task Force leader, Vice President Pence, to pursue.

Increased Testing Figures Prominently in the Plan

Another bit of welcome news to the lab industry is the commitment to scale and expand COVID-19 testing. "To control the COVID-19 pandemic and safely reopen schools and businesses, America must have wide-spread testing," the National Strategy declares. "A national testing strategy is a cornerstone to reducing the spread of COVID-19 and controlling outbreaks, and clear federal guidance and a unified national approach to implementation are essential." A key part of the National Strategy is direct involvement by the federal government to expand supplies of rapid tests, double test supplies and increase testing capacity.

The Pandemic Testing Board Executive Order

The administration has already taken steps to execute the National Strategy. Among the new President's first Executive Orders is one

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Glenn S. Demby, Executive Editor

Barbara Manning Grimm, Managing Editor

Jim Pearmain, General Manager

Andrea Stowe, Business Development

Pete Stowe, Managing Partner

Mark T. Ziebarth, Publisher

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.

that establishes the COVID-19 Pandemic Testing Board to oversee implementation of a clear, unified approach to testing. The Executive Order directs agencies to facilitate testing free of charge for those who lack health insurance and to clarify insurers' obligation to cover testing. The federal government will also provide testing protocols to inform the use of testing in congregate settings, schools, and other critical areas and among asymptomatic individuals. Further, technical assistance will support more widespread adoption of testing to improve timely diagnosis and public confidence in the safety of settings like schools.

The DPA Executive Order

Another dramatic difference in approach is the new administration's willingness to use the DPA to promote the production of vaccines, tests, PPE, reagents and other critical testing materials that have been in short supply. With that in mind, the President issued a separate Executive Order directing federal agencies to exercise the DPA and other applicable legal powers to get industry to accelerate the manufacturing, delivery and distribution of 12 categories of critical supplies, including taking action to increase the availability of supplies including:

- N95 masks, isolation gowns, nitrile gloves and other PPE;
- PCR sample collection swabs;
- Test reagents;
- Pipette tips;
- Lab analysis machines for PCR tests;
- High-absorbency foam swabs and nitrocellulose material for rapid antigen tests;
- Rapid test kits;
- Low dead-space needles and syringes; and
- Necessary equipment and material to accelerate the manufacture, delivery, and administration of COVID-19 vaccine.

$50 Billion More for COVID-19 Testing

The administration's new relief package is also putting the money where the National Strategy's mouth is. Thus, the proposed $1.9 trillion American Rescue Plan includes $50 billion to expand COVID-19 testing and $30 billion more to the Disaster Relief Fund to help ramp up production of supplies including items like vials, reagents, and protective gear that are essential to collecting and running clinical samples.

Lab Industry Response

The initial response from the lab industry has been largely positive. In a statement, American Clinical Lab Association (ACLA) president Julie

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Khani, "commend[ed] President Biden for taking a national, science-driven approach to combatting COVID-19. . . . and [giving] public health officials additional tools they need to combat this devastating virus."

Mark Birenbaum, executive director of the National Independent Laboratory Association (NILA), also praised the National Strategy, including the proposed funds for testing and protective supplies. He added, however, that NILA member labs would also like to see more efforts to provide transparency around how those supplies are distributed.

Takeaway

The point of this analysis is not to contend that the Biden approach to COVID-19 response is superior to that of the Trump administration. For those who believe in limited federal government, the National Strategy is bound to be most disconcerting and even horrifying. But elections have consequences and the fact is that the new President is going at things in a diametrically opposite way from his predecessor with a willingness to leverage every bit of federal government power and authority to tackle the crisis. It's the same approach that Lincoln and Franklin D. Roosevelt followed to confront the national emergencies they faced. Whether it's the right strategy and will prove effective for COVID-19 remains to be seen.

Industry Buzz: Myriad Genetics Puts Its Autoimmune Division Up for Sale

What a difference a pandemic makes! Last year at this time, molecular genetic testing was a fairly soft market. But the unprecedented and unexpected demand for COVID-19 diagnostics has lifted the revenues of genomics firms to incredible levels. Regrettably, not all companies in the molecular diagnostics space have shared in the prosperity. And now one of the most established and respected of these have-not genomics firms has decided put a part of itself up for sale.

Tough Times for Myriad Genetics

Founded in 1991—10 years before the human genome was sequenced—Myriad Genetics was one of the first genomics companies in history and a pioneer in molecular tests for cancer, autoimmune disorders, depression and other hereditary diseases. In 2020, it generated nearly $637 million in revenues led by a stable of products that includes the Prolaris cancer

prostrate, EndoPredict, Vectra DA rheumatoid arthritis and GeneSight pharmacogenetics tests.

However, a soft market, coverage denials and sagging reimbursements have caused the firm to struggle in recent years. Revenues fell, share prices declined and analysts grew restless. When the pandemic came, things went from bad to worse. Myriad wasn't positioned to provide viral diagnostic testing the way many other genomics firms were. Nor did it pivot to meet the demand for COVID-19 diagnostics. Consequently, while competitors were reaping double- and even triple-digit growth, Myriad saw double-digit decline, with total revenues falling 22 percent in 3Q of 2020, including a 21 percent drop in core molecular diagnostics. Just about all product lines took a hit, including:

- Prolaris—down 2 percent;
- GeneSight—down 48 percent;
- Vectra DA—down 17 percent; and
- Women's health division products, including myRisk Hereditary Cancer, Foresight and Prequel—down 34 percent.

Myriad Makes a Strategic Decision

Myriad executives have been hard at work performing strategic review and plotting initiatives to stem the bleeding via simplification of the business, adjustment of the cost base and development of new commercial capabilities. And on Jan. 6, 2021, the company announced a key decision: it would reorganize its international operations and seek a buyer for its autoimmune business, including the Vectra DA test.

Although it accounted for over $40 million in annual revenues before the pandemic, Vectra DA has been in steady decline. Rather than seek to turn things around, Myriad will sell off the test and rest of the autoimmune division to focus on core hereditary tests. "We believe the growth prospects for this product are even more significant in an organization with greater focus and complementary capabilities in autoimmune disease," noted Myriad President and CEO Paul Diaz in a statement.

The Vectra DA decision comes a couple of months after Myriad indicated that it was planning to sell off its Myriad RBM pharmaceutical contract research services business and myPath Melanoma dermatology test. These divestments are part of a larger plan in which Myriad will initially focus on recovering from the pandemic by implementing a $40 million cost savings plan over the next nine months and investing $20 million to improve marketing and customers' experience. In phase two, the company will refocus on key growth initiatives and improving financial performance. In the third phase, Myriad will invest in new innovations and potential M&A opportunities.

FDA WATCH

Ortho Clinical Diagnostics Gets Green Light for Mass SARS-CoV-2 Antigen Test

Almost from the moment the pandemic began, high throughput testing for use in mass screening has occupied a high place on the FDA's coronavirus diagnostics priority list. On Jan. 12, 2021, Ortho Clinical Diagnostics announced that it has received FDA emergency use authorization (EUA) for what it claims is the first high-volume SARS-CoV-2 antigen test cleared for such use.

The Vitros SARS-CoV-2 Antigen Assay

Ortho's Vitros SARS-CoV-2 Antigen test is well positioned to meet the need for mass screening because it runs on the firm's high-volume Vitros systems (namely, the Vitros 3600 Immunodiagnostic and Vitros 5600/ XT 7600 Integrated systems) that are installed in more than 5,600 labs worldwide, including 1,500 in the U.S. These systems are capable of running up to 130 of the newly cleared Vitros SARS-CoV-2 tests per hour, according to the Raritan, N.J.-based firm.

Unlike most antigen tests which detect the virus samples of blood and bodily fluids, the Ortho test can be used on swabs collected in accordance with the U.S. Centers for Disease Control and Prevention's (CDC) formulation of viral transport media (VTM), Copan Universal Transport Media, Remel M4RT VTM or Hard R99 VTM. Samples can be collected in bulk, stored at room temperature for up to 24 hours (or 48 hours with refrigeration).

Ortho claims that the antigen test is a viable alternative to RT-PCR for people with known or suspected exposure to SARS-CoV-2 or who are displaying symptoms suggestive of infection. With 97.8 percent sensitivity and 99.2 percent specificity, the test "offers exceptional utility for mass-scale testing where appropriate," according to a company statement.

Next Steps for Ortho

Ortho has established itself in the non-RT-PCR coronavirus assay market in the U.S. and globally. The Vitros antigen assay received CE clearance for use in Europe in October. Shortly after, the firm scaled up production in the U.K. Now that the test has received EUA, the company expects to step up production out of its Rochester, N.Y., manufacturing facility.

The antigen test expands the Ortho COVID-19 product portfolio which includes a pair of antibody tests that have both received CE marking in Europe and FDA EUA clearance in the U.S. One test detects total antibodies to SARS-CoV-2 and the other detects IgG antibodies. The firm has also received a $12.9 million grant from the U.S. Department of Health and Human Services' Biomedical Advanced Research and Development Authority (BARDA) to develop its trio of SARS-CoV-2 tests.

Ortho said that it currently can deliver 5 million tests per month and that it will be able to increase that figure to 15 million tests per month in February.

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Here are the other key new FDA EUAs and international clearances announced in January 2021:

New FDA Emergency Use Authorizations (EUAs) & Approvals

Manufacturer(s)	Product
Ambry Genetics	EUA for Ambry COVID-19 RT-PCR Test
Bio-Rad Laboratories	EUA for Bio-Rad Reliance SARS-CoV-2 RT-PCR Assay
United Biomedical	EUA for UBI SARS-CoV-2 ELISA antibodies test
SML Genetree	EUA for Ezplex SARS-CoV-2 G Kit
Ortho Clinical Diagnostics	Vitros SARS-CoV-2 Antigen test, first high-volume COVID-19 antigen test to get EUA
Phadia (Thermo Fisher Scientific subsidiary)	EUA for EliA SARS-CoV-2-Sp1 IgG Test fluoro-enzyme immunoassay
Abbott	510(k) clearance for rapid handheld blood test for traumatic brain injury
Helix	*de novo* clearance for Helix Laboratory Platform, first whole-exome sequencing platform to get FDA clearance
Helix	510(k) clearance for Helix Genetic Health Risk App (HRA) DTC genetic test for late-onset Alzheimer's
Siemens Healthineers	EUA for Dimension Vista SARS CoV 2 IgG (COV2G) antibodies immunoassay
Siemens Healthineers	EUA for lab-based IL-6 assay to measure presence of interleukin-6 in human serum or plasma
Advaite	EUA for RapCov Rapid COVID-19 Test point of care serology test
Quanterix	EUA for Simoa SARS-CoV-2 N Protein Antigen Test
Nirmidas Biotech	EUA for MidaSpot COVID-19 Antibody Combo Detection Kit point of care test
Roche	EUA for Elecsys Anti-SARS-CoV-2 S electrochemiluminescence immunoassay run on firm's Cobas E analyzers
Lucira Health	EUA for Lucira COVID-19 All-in-One Test Kit, first fully at-home test authorized for COVID-19
GenScript Biotech	EUA for cPass SARS-CoV-2 Neutralization Antibody Detection Kit, first SARS-CoV-2 neutralizing antibody test to receive EUA

New CE Marks & Global Certifications

Notable European CE certifications announced during the period:

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FDA Watch, *from page 7*

NEW CE MARKINGS IN EUROPE

Manufacturer(s)	Product(s)
Fluidigm	Advanta Dx SARS-CoV-2 RT-PCR assay
Abbott	Panbio COVID-19 Ag Rapid Test Device for mass screening of the asymptomatic and self-swabbing
Actim	Actim ELISA SARS-CoV-2 IgG assay
Chembio Diagnostics	DPP SARS-CoV-2 Antigen and IgM/IgG test systems
Biomerica	COVID-19 Rapid Antigen Test
Theradiag	4 biotherapy monitoring test kits run on firm's i-Track 10 system and Immunodiagnostic Systems' IDS-iSYS automated analyzer: *i-Tracker Vedolizumab *i-Tracker Anti-Vedolizumab *i-Tracker Ustekinumab *i-Tracker Anti-Ustekinumab
Snibe Diagnostic	Maglumi SARS-CoV-2 Neutralizing Antibody Assay
Spectrum Solutions	Two SDNA saliva collection devices for molecular testing
Trinity Biotech	Captia SARS-CoV-2 IgG ELISA test
Shuwen Biotech	SARS-COV-2 RT-PCR Kit
Sona Nanotech	Rapid SARS-CoV-2 antigen test
BioPorto	NGALds point-of-care kidney injury test

Other international clearances announced during the period:

Manufacturer(s)	Country(ies)	Product(s)
LumiraDx	Japan	SARS-CoV-2 Antigen test
LumiraDx	Brazil	SARS-CoV-2 Antigen test
DNA Genotek (OraSure Technologies subsidiary)	Canada	OMNIgene ORAL (OME-505) saliva collection device for use in SARS-CoV-2 molecular testing
MiRxes	Singapore	Multiplex SARS-CoV-2 and influenza A/B test
Excalibur Healthcare Services	U.K.	Rapid SARS COV-2 Antigen Screening test
GNA Biosolutions	Germany	Octea SARS-CoV-2 batch testing system

M&A Report: Hologic Turns COVID-19 Testing Cash into Strategic Acquisitions in Core Women's Health Space

M&A deal making in the diagnostics marketing is off to a very fast start in 2021. The biggest deal announced in January was PerkinElmer's bid to expand its infectious disease testing capabilities by acquiring U.K.-based immunology firm Oxford Immunotec for $491 million (with the potential to rise to $591 million). However, the most aggressive player in space was Hologic, which made a pair of key acquisitions.

The $230 Million Biotheranostics Acquisition

On Jan. 6, Hologic announced plans to acquire San Diego-based, privately held Biotheranostics for $230 million. The deal makes perfect sense. Biotheranostics' cancer genetics diagnostics products for breast and metastatic cancers, including the PCR-based Breast Cancer Index and CancerType ID tests (the former of which is included in clinical practice guidelines for breast cancer), are a perfect fit that will provide a boost to Hologic's position in women's health and diagnostic testing. Collectively, the Biotheranostics' products generated $33 million in revenues in 2020.

The deal, which is scheduled to close in February, means that patients facing the challenges of metastatic cancer will have broader access to the CancerType ID offering that can aid in the diagnosis of the tumor type and subtypes representing 95 percent of all solid tumors, noted Biotheranostics' CEO Don Hardison in a statement.

The $64 Million Somatex Medical Acquisition

Announcement of the Biotheranostics acquisition came just two days after Hologic announced the closing of still another women's health provider, Somatex Medical, for $64 million. In addition to boosting Hologic's presence in Europe, acquisition of the Berlin-based manufacturer of minimally invasive devices for tumor diagnostics, biopsy and interventional specialties furthers the company's global objective to provide comprehensive breast healthcare portfolio.

There May Be More to Come

The back-to-back deals in the first week of the new year signifies that Hologic is determined to remain focused on its core women's health business even though it's currently reaping huge revenues in COVID-19 testing. Of course, COVID-19 testing is providing the cash flow that enables Hologic to make these strategic moves. And there's a pretty good chance that Hologic's shopping spree will continue. The company posted $1.35 billion in revenues last year—and that was just in Q4! "Using our strong cash flow to further expand our core businesses into large, fast-

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growing adjacencies is a key goal of our capital deployment strategy," noted Hologic Chairman, President and CEO Steve MacMillan in announcing the Somatex deal.

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Here's a summary of the only key new M&A diagnostic deals announced in January 2021:

MERGERS, ACQUISITIONS & ASSET SALES

Acquiring Company	Target(s)	Deal Summary
Thermo Fisher Scientific	Mesa Biotech	• Price: Up to $591 million including $491 million cash up front and up to $100 million cash if milestones reached • Status: Expected to close in Q1 • Acquisition of molecular test firm with 500 employees that sells PCR-based rapid point-of-care platform for infectious diseases, including SARS-CoV-2, influenza A and B, RSV and Strep A
PerkinElmer	Oxford Immunotec	• Price: $591 million cash representing $22 for each outstanding share of Oxford, a 28.3% premium on Jan. 5 closing price • Status: No closing date announced • Acquisition enables PerkinElmer to add tuberculosis detection to its infectious disease testing portfolio
GTCR equity firm Cole-Parmer	ZeptoMetrix	• Price: Undisclosed • Status: Closed • Acquisition of maker of quality control standards and verification panels for infectious disease molecular testing
Hologic	Biotheranostics	• Price: $230 million • Status: Expected to close in February • Acquisition of producer of molecular tests for breast and metastatic cancers boosts Hologic's position in women's health market

Acquiring Company	Target(s)	Deal Summary
Hologic	Somatex Medical Technologies	• Price: $64 million • Status: Closed • Acquisition of manufacturer of minimally invasive devices for tumor diagnostics, biopsy and interventional specialties furthers Hologic's objective to provide comprehensive breast healthcare portfolio
MilliporeSigma	AmpTec	• Price: Undisclosed • Status: Closed • Acquisition of Germany-based mRNA contract development and manufacturing organization boosts MilliporeSigma's capacity to provide mRNA for vaccines, treatments and diagnostics
MyDNA	Gene by Gene	• Price: Undisclosed • Status: Closed • Merger combining MyDNA's genetic wellness tests for nutrition, fitness, and skincare with Gene by Gene's (and its FamilyTreeDNA business') genetic testing services for ancestry, forensics, paternity and COVID-19

DX Deals: Global Collaboration Seeks to Develop Game-Changing Handheld COVID-19 Breathalyzer Test, *from page 1*

People displaying symptoms of illness should be the priority when testing resources are in scarce supply. By the same token, the coronavirus is mostly spread by persons who don't have symptoms. That makes it imperative to develop a method of providing mass testing to asymptomatic people *without* diverting resources desperately needed for testing the symptomatic.

The Potential for VOCs Testing

Current COVID-19 diagnostics, including laboratory developed tests (LDTs), are based molecular, antibodies or antigen detection. A potential solution is to develop a new modality using a different biomarker to detect the virus. One candidate is exhaled volatile organic compounds (VOCs) that could be detected via a rapid breath test. And that's the idea behind the new research collaboration between Canary Health Technologies and Divoc Laboratories.

The Collaboration

Announced on Nov. 30, the objective of the collaboration between Canary and Divoc is to develop and validate a handheld digital breath test for coronavirus. Canary is a U.S.-based medical technology company that uses proven biomarkers, proprietary nanosensors and AI-powered software to map and uncover data in human breath to detect cancers, inflammatory and infectious diseases on a rapid basis. Divoc is a Dehli-based lab focused on providing a digitally empowered integrated approach to diagnostics.

The new Canary test, called ASU Detect CV19, uses next-generation, highly sensitive nanosensors to collect breath samples which are then analyzed through the use of cloud-based artificial intelligence capable of detecting the SARS-CoV-2 virus in less than three minutes. In addition to being disposable, which mitigates the risk of infection, the Canary test is scalable, low cost and viable for use at the point of care for mass screening of both the symptomatic and asymptomatic.

The Next Steps

The idea is exciting. The key question, of course, is whether it will actually work. In 2019, a clinical trial in Canada demonstrated that the Canary breath analysis platform is capable of detecting lung cancer with high sensitivity and specificity. To validate the concept for use with coronavirus, the partners are carrying out what they describe as the first and largest clinical trial using a real-time breath test using cloud-based artificial intelligence for pattern recognition to detect an infectious disease.

To be performed in Dehli, the trial researchers will collect breath samples from 750 people, including both COVID-19-positive patients and patients

who don't have the virus. They'll be asked to breathe for three minutes into the device. The ASU device will then translate their breath biomarkers into electronic signals which will be transmitted to a centralized "lab in the cloud" for analysis. The partners also plan to start parallel trials in the U.S. and Europe.

If the trial is successful, Canary plans to seek fast-track regulatory approval in India, the U.S. and other markets while continuing to trial the test in real-world settings such as airports, resorts and other high-density areas.

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Here's a summary of other key strategic diagnostic deals announced in January 2021:

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS

Partner 1	Partner(s) 2+	Deal Summary
Invitae	Bristol Myers Squibb + Janssen Research & Development + Novartis + Genentech	• Objective: Develop NGS-based panel for standardized minimal residual disease (MRD) detection in acute myeloid leukemia (AML) patients • Dynamic: Leverage Invitae's anchored multiplex PCR chemistry to standardize MRD measurement methods for use in clinical trials assessing effectiveness of AML treatments and as biomarker for predicting patient survival after treatment
Invitae	Pacific Biosciences	• Objective: Develop production-scale, high-throughput whole-genome sequencing (WGS) platform for clinical use • Dynamic: Multi-year collaboration to leverage PacBio's HiFi long-read next-generation sequencing to develop cost-effective assays and make WGS-powered analysis more accessible for carrier screening, evaluating immune system responses and diagnosing other heritable disease • Companies currently collaborating to use HiFi sequencing to develop new epilepsy diagnostics

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DX Deals, *from page 13*

Partner 1	Partner(s) 2+	Deal Summary
Illumina	Helix	• Objective: Track new SARS-CoV-2 strains in U.S., including B.1.1.7 variant first identified in U.K. • Dynamic: With CDC support, Helix to analyze positive samples with S gene dropout on their PCR-based COVID-19 assay; Illumina to then use its COVIDSeq test to sequence a subset of anonymized samples to determine whether dropout is due to strain B.1.1.7 or a different mutation
Oxford Immunotec	Valneva	• Objective: Perform T-cell testing for Valneva's COVID-19 vaccine candidate VLA2001 • Dynamic: Oxford Immunotec (which is being acquired by PerkinElmer) to use its research-use-only T-Spot Discovery SARC-CoV-2 test on participants getting VLA2001 vaccine
Tempus	A2 Biotherapeutics	• Objective: Develop companion diagnostic test for Tmod, A2's loss of heterozygosity (LOH)-targeted cell therapy platform • Dynamic: LOH CDx assay to run on Tempus' xT sequencing platform to identify patients eligible for Tmod • Partnership may expand to include development of additional CDx tests for A2's other clinical development programs
Qiagen	Personal Genome Diagnostics	• Objective: Provide clinical decision support to users of PGDx's cancer genomic profiling tests • Dynamic: Non-exclusive agreement offering labs that purchase PGDx Elio oncology products option to receive standardized reporting from Qiagen based on professional guidelines to facilitate case review • Labs to also get access to Qiagen's QCI Interpret One for rapid, evidence-based variant interpretation and reporting for NGS tests
Biodesix	HiberCell	• Objective: Develop enzyme-linked immunosorbent assay (ELISA) for use as companion diagnostic test • Dynamic: Biodesix to develop CDx test to select patients for enrollment in future HiberCell clinical trials

Partner 1	Partner(s) 2+	Deal Summary
Resolution Bioscience	Mirati Therapeutics	• Objective: Develop CDx to identify non-small cell lung cancer (NSCLC) patients who may benefit from Mirati's investigational KRAS G12C inhibitor therapy • Dynamic: Leverage Resolution's ctDx liquid biopsy technology to identify NSCLC patient candidates
Grail	Amgen + AstraZeneca + Bristol Myers Squibb	• Objective: Evaluate Grail's methylation-based technology for detecting MRD in early-stage cancer patients • Dynamic: Grail to use results to adapt its targeted methylation platform for cancer screening for use to screen cancer patient's blood for signs of MRD, a simpler solution not requiring upfront tissue samples or personalized assays
Clear Labs	Integrated DNA Technologies	• Objective: Automate and improve accuracy of Clear Dx SARS-CoV-2 assay • Dynamic: Expansion of previous agreement covering oligonucleotide supply agreement for food safety testing
Genuity Science	Emory University	• Objective: Develop population clinicogenomic database to support biomarker and drug target discovery and validation • Dynamic: Partnership to focus initially on neurogenerative conditions, including Alzheimer's and Parkinson's
CareDx	IDbyDNA	• Objective: Develop metagenomic infectious disease testing for transplant patients • Dynamic: Exclusive partnership to develop and commercialize AlloID, infectious disease test tailored to organ transplant donors and recipients that identifies over 100 pathogens, as well as drug resistance in viruses and bacteria
Sera Prognostics	Anthem and its HealthCore insurer subsidiary	• Objective: Determine if Sera's PreTRM test can lead to improved health for newborns and mothers • Dynamic: Perform study to evaluate how pairing PreTRM test with clinical interventions may mitigate preterm birth risk, improve neonatal outcomes and reduce overall healthcare costs in this population

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DX Deals, *from page 15*

Partner 1	Partner(s) 2+	Deal Summary
4D Lifetec	VolitionRx	• Objective: Determine whether combining each firm's respective assay technology can improve identification of individuals with early-stage cancer • Dynamic: Perform clinical validation trial using 4D's 4D Lifetest in combination with Volition's NuQ technology in a set of lung cancer clinical samples

DISTRIBUTION, SALES & MARKETING AGREEMENTS

Product Owner	Distributor	Deal Summary
GenapSys	Bioron	• Products: GenapSys' sequencing system • Territories: Germany
Phasefocus	Cellink	• Products: Phasefocus' Livecyte high-content live-cell imaging platform • Territory: Undisclosed • Cellink to offer Livecyte in combination with its own bioprinters, liquid handlers and bioinks products
Mission Bio	Bioké	• Products: Mission Bio's Tapestri single-cell multi-omics platform • Territory: Netherlands, Belgium, Luxembourg
LevitasBio	Bioké	• Products: LevitasBio's LeviCell cell separation system • Territory: Netherlands, Belgium, Luxembourg
PixCell Medical	Triolab	• Products: PixCell's HemoScreen Hematology Analyzer • Territory: Sweden • Exclusive
Access Bio	Everlywell	• Products: Access Bio's CareStart COVID-19 antigen test • Territory: U.S. • Test to be distributed to organizations in need
Curetis (OpGen subsidiary)	Annar Health Technology	• Products: Curetis Unyvero A50 instrument and Unyvero infectious disease diagnostic application cartridges • Territory: Colombia • 3-year deal with 1-year renewal options under which Annar commits to purchase at least 10 Unyvero instruments and a large number of Unyvero cartridges

LICENSES

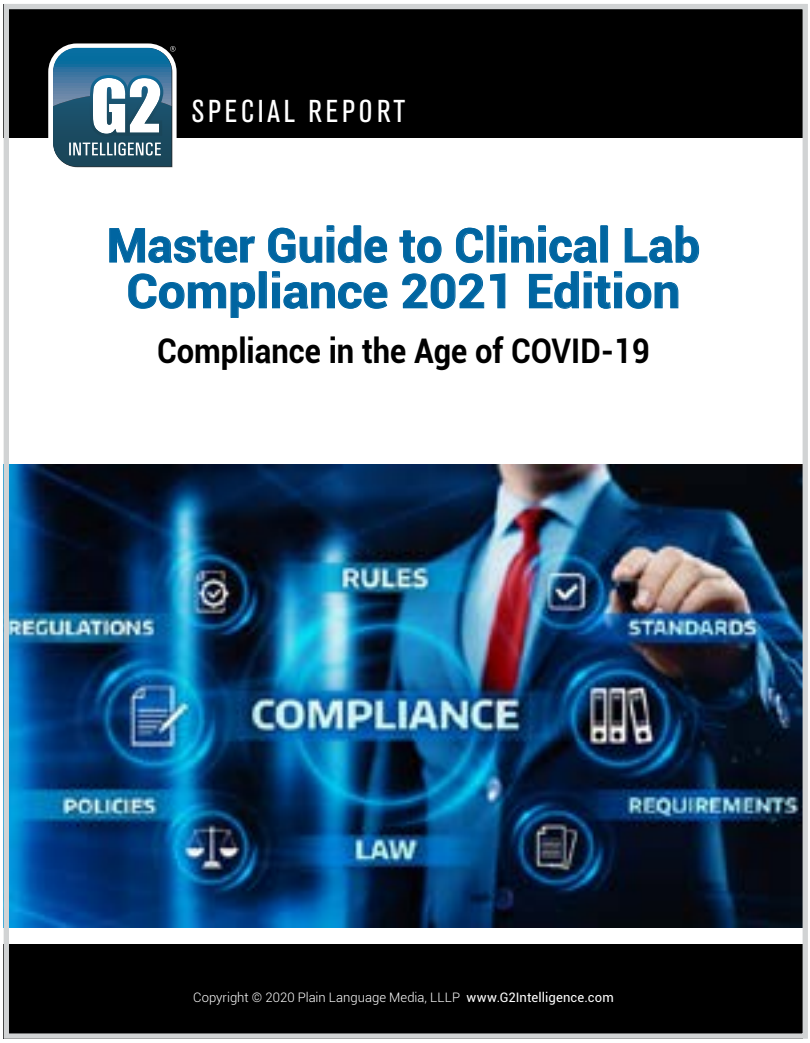
Licensor	Licensee	Deal Summary
Procter & Gamble	Rhinostics	Rhinostics licenses plastics technology for novel nasal swab to relieve COVID-19 testing supplies bottlenecks

SUPPLY, SERVICE, TESTING & MANUFACTURING AGREEMENTS

Supplier/ Servicer	Client/User	Deal Summary
Nexus Dx	Osang Healthcare	Nexus Dx to manufacture Osang's GeneFinder COVID-19 Plus RealAmp Kit kit at its San Diego facility

Master Guide to Clinical Lab Compliance 2021

Compliance in the Age of COVID-19



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