G2 INTELLIGENCE
A DIVISION OF PLAIN LANGUAGE MEDIA

Your Independent Source for Business & Financial News

LABORATORY INDUSTRY REPORT™

Vol. 21, Iss. 10
October 2021

IN THIS ISSUE

G2Intelligence.com

In the News: Becton Dickinson Gets EUA for At-Home COVID-19 Antigen Test Providing Results by Phone

At-home rapid SARS-CoV-2 antigen testing has become a gold mine. Expanding availability, affordability and use of those tests is a central element of President Biden's new COVID-19 response plan. The administration will purchase nearly $2 billion worth of these tests—280 million total tests—from multiple manufacturers. And now comes word of what could be a product game changer. In late August, Franklin Lakes, NJ-based Becton Dickinson (BD) announced in late August, that its BD Veritor At-Home COVID-19 Test using computer vision technology in a smartphone to interpret and provide a digital display of COVID-19 testing results has received Emergency Use Authorization (EUA) from the FDA.

Continued on page 2

DX Deals: Twist Bioscience Unveils 3 New Strategic Collaborations for Synthetic Biology Discovery

High-quality synthetic DNA powers molecular research and the discovery and development of innovative new diagnostic products. Twist Bioscience has developed a proprietary process featuring a high-throughput silicon platform for miniaturization. It's a lot like the process used in the semiconductor industry applied to miniaturize chemistry needed for DNA synthesis. The Twist platform is capable of synthesizing 9,600 genes on a single chip, as compared to the single gene produced by traditional methods in the same footprint.

Continued on page 11

In the News: Becton Dickinson Gets EUA for At-Home COVID-19 Antigen Test Providing Results by Phone, *from page 1*

The Veritor Test

The BD Veritor Test, which doesn't require a prescription, uses a nasal swab and a mobile app from Scanwell Health that can yield test results in as soon as 15 minutes. The app is available on iOS and Android and provides step-by-step instructions on how to collect and transfer the nasal swab sample to the test stick. The mobile device's camera is then used to capture, analyze and interpret the results, which eliminates the human subjectivity of a visually read test.

BD says its test is designed to be easily performed at home by people 14 years of age or older. The test can also be used for children as young as two-years-old with samples collected by an adult.

BD will initially make the test available to businesses, schools and governments looking to provide a self-testing option for employees or students.

"The rise in COVID-19 cases from the Delta variant has increased the demand for at-home testing, and the BD Veritor At-Home COVID-19 Test is an easy-to-use test with definitive digital results that is ideal for use in the home," noted Dave Hickey, BD president of Life Sciences in a press release. "New mandates from governments and businesses are specifying the need for periodic testing for those who cannot or chose not to be vaccinated, and this new test may help businesses, governments or schools fulfill those requirements," he added.

LIR

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.

Litigation Update: Labs and Payors Take Their COVID-19 Test Reimbursement Feud to Court

The very public feud between health insurers and labs over payment of COVID-19 tests has just entered a new stage: litigation.

FFCRA, CARES & the Free Test Mandate

On March 18, 2020, at the start of the public health emergency, Congress enacted the *Families First Coronavirus Response Act* (FFCRA) requiring group health plans and health insurers offering group or individual health insurance coverage (but not short-term health plans) to provide benefits for certain items and services related to diagnostic testing for SARS-CoV-2. To ensure that testing is free, (Section 6001 of) FFCRA banned deductibles, copayments and coinsurance, prior authorization and other standard methods used by payors to control utilization and costs.

Exactly one week later, FFCRA was amended via passage of the *Coronavirus Aid, Relief, and Economic Security Act* (CARES) which, among other things, broadened the range of diagnostic items and services subject to the Section 6001 coverage without cost-sharing or prior authorization mandate. CARES also required payors to reimburse providers of "medically appropriate" COVID-19 diagnostic testing an amount equal to their negotiated rate with the provider; if there was no negotiated rate, reimbursement had to be at the cash price for such service listed by the provider on a public website. CARES also gave payors the greenlight to negotiate for—but not unilaterally impose—a rate lower than the provider's listed cash price.

The PR War Over COVID-19 Test Reimbursement

From the very onset, labs and payors have clashed over the extent of the free testing mandate. Testing labs have repeatedly accused insurers of failing to provide reimbursement for COVID-19 tests in defiance of the federal mandate. Health insurance groups have responded by accusing labs of price gouging.

Insurers escalated the PR war last November in the form of a study supposedly documenting overcharging of labs for COVID-19 tests. The study from America's Health Insurance Plans (AHIP) based on data from survey of 22 members, representing 76 percent of commercial enrollment of the trade group's member plans, found that, on average, a test in the commercial market costs $130, and out-of-network tests cost more than $185. Its conclusion: "Between 9 percent and 16 percent of out-of-network test claims charged more than $390 (three times the average cost)."

The Genesis Lawsuit against UnitedHealth

A new front in the conflict opened on June 2 when medical testing lab Genesis Laboratory Management sued UnitedHealth Group in the U.S District Court for the district of New Jersey. UnitedHealth paid the majority of the out-of-network molecular diagnostic and anatomic pathology lab's claims for March, April and May 2020. However, the suit contends, United and its Oxford Health Plans Group began "systematically denying" payment for claims starting in June, even though the lab didn't change its testing, billing or documentation practices. Genesis contends that it has never refused to treat United members despite the insurer's failure to pay and despite its demands that the lab "produce voluminous patient treatment and other records with tight response time demand."

In addition to FFCRA and CARES, Genesis claims that United violated a pair of New Jersey state laws, including the:

- *Healthcare Information Networks and Technologies Act; and*
- *Health Claims Authorization, Processing and Payment Act.*

Continued on page 4

Litigation Update: Labs and Payors Take Their COVID-19 Test Reimbursement Feud to Court, *from page 3*

The complaint also accuses UnitedHealthCare with breach of implied contract, breach of the covenant of good faith and fair dealing and unjust enrichment, among other things. "Genesis has been, and continues to be, harmed by United's failure to pay valid claims that Genesis submitted to United for reimbursement for services to United's members and beneficiaries," the complaint states.

Blue Cross and Blue Shield Sues Lab for Price Gouging

Insurers have now resorted to the litigation card. Blue Cross and Blue Shield of Kansas City is suing GS Labs for COVID-19 test price gouging, contending that the national testing facility inflated its cash prices and performed medically unnecessary tests on out-of-network members.

The $9.2 million federal lawsuit accuses GS Labs of "engaging in an abusive scheme to exploit the COVID-19 pandemic by duping health insurers into paying thousands of COVID-19 diagnostic testing claims at grossly inflated rates." BCBS claims that GS Labs charged it $380 for a COVID-19 antigen test, roughly 10 times what Medicare reimburses for the test and up to $979 for a PCR test.

This is not the first time that GS Labs' test prices have come under question. Last December, the Kansas Insurance Department began investigating a local facility owned by GS Labs for charging $1,000 for tests. GS Labs has yet to comment on these allegations.

Takeaway

So far, the battle over reimbursement of COVID-19 testing has focused on testing of the symptomatic. Seizing on a loophole in the CMS guidance defining "medically appropriate" tests covered by CARES as applying to the symptomatic, health insurers have refused to pay for rapid tests performed on asymptomatic persons by employers, schools and other institutions for purposes of screening.

Reimbursement: New LCD Expanding Medicare Coverage for Circulating Tumor Cells Tests Is a Win for Biocept

Biocept announced that it has received expanded Medicare coverage for use of its Target Selector assay to identify HER-2 positive circulating tumor cells under a final CMS local coverage determination (LCD) that took effect on July 4.

The New LCD for CTC Tests

Although the LCD doesn't mention any particular test brand or technology by name, it does outline Medicare coverage criteria for circulating tumor cell (CTC) assays. Tests that detect biomarkers from CTC may be covered when used in cancer types with established biomarker testing that meets national guidelines or the recommendations of a recognized professional society. The LCD outlines four basic criteria for coverage:

1. Use Must Be Appropriate

Appropriate uses include diagnosis, risk stratification, prediction, or monitoring of therapy response, where these actions have recognized clinical utility.

2. Rationale for Testing Must Be Appropriate

The CTC test is covered only if either:

- The patient is newly diagnosed and not previously tested; or
- There's an established rationale for retesting such as demonstrated disease progression or suspicion of treatment resistance.

3. Test Technology Must Be Validated

Even if the first two criteria are met, Medicare will cover the assay only if the CTC test technology has successfully completed a comprehensive technical assessment ensuring analytical validity that's equivalent or superior to tissue-based testing or another already-accepted test for the same biomarker for the same intended use.

4. Tissue-Based Alternatives Not Feasible

In addition to these criteria, CTC testing is covered under the LCD only if:

- Tissue-based testing for the biomarker in question is infeasible;
- Repeat biopsy is medically contraindicated; or
- Tissue testing won't provide information sufficient for subsequent medical management, e.g., in cases where HER2 overexpression is negative in a tissue biopsy but may be positive in CTCs, due to tumor heterogeneity.

Takeaway

Biocept said its Target Selector CTC HER2 test has passed the CMS technology review, required by the second criterion. And because HER2 testing is a mainstay of precision oncology and mandated by professional guidelines for all patients with new primary or newly metastatic breast cancer, Medicare should cover the assay when used for individual cases that meet the LCD criteria, including those relating to the unavailability of testing on tissue samples.

Inside the Lab Industry: Tech Giants Continue Efforts to Disrupt Healthcare Despite Google Health Shutdown

Another attempt by an outsider to disrupt the healthcare market is apparently coming to an end. According to a leaked internal memo, after three years of operation, Google has decided to unwind its Google Health division. The memo, which was obtained by online media company *Business Insider*, was sent to Google employees in mid-August, just days after the announced departure of the division's CEO David Feinberg.

The Rise(s) and Fall(s) of Google Health

Google hired Feinberg, who was then serving as CEO of Geisinger Health, to head the newly created Google Health division in 2018. His mission was to coordinate and lead various health projects operated by Google's parent company, Alphabet. Those projects will now be reorganized with the health teams becoming part of Google's research, search and device divisions. Meanwhile, Feinberg is moving on to become CEO of EHR giant Cerner.

Google has been down this road before. The company launched its first healthcare initiative, a personal healthcare records venture also called Google Health, back in 2009 before closing it down four years later. The original Google Health was similar to Microsoft Corp.'s HealthVault, which also shuttered in 2019 after 12 years of operation.

Google, Amazon, Microsoft Forge Ahead

The closing of the most recent incarnation of Google Health in no way signals the end of the search engine giant's exit from the healthcare realm. "Google deeply believes in the power of technology to improve health and wellness and we have increased our health investments across the company," according to an email from a Google spokesperson cited in the *Business Insider* story. "Today, health is a growing, company-wide effort and the Google Health name will continue and encompass our projects that share the common purpose to improve global health outcomes."

To that end, Google hasn't disbanded the Google Health teams but rather reassigned them to other research ventures, including Fitbit, which Google acquired in January 2021. Google's YouTube also formed its own health team earlier this year dedicated to addressing consumers' digital health needs.

In addition, Google will maintain its cloud storage and innovation arrangement with the Mayo Clinic. Two years ago, Mayo Clinic created a clinical data analytics platform on Google's cloud platform. The firms also launched a joint research project to study whether AI can automate aspects of radiation therapy planning.

And of course, Amazon and Microsoft will continue their own efforts to develop new cloud-based game changers in the health care space. But disrupting healthcare isn't easy, even for proven companies who've demonstrated their business genius in other sectors.

FDA WATCH

Agency Tells EUA SARS-CoV-2 Test Makers to Account for Viral Mutations

On Sept. 23, FDA issued a letter requiring producers of SARS-CoV-2 tests with Emergency Use Authorization (EUA) to take additional steps to account for viral variants. The new Conditions of Authorization apply to certain molecular, antigen and serology tests that have already received EUA for SARS-CoV-2 diagnosis and detection. They don't cover EUAs for authorized IL-6 assays, standalone specimen collection devices, or standalone home collection kits. Nor do they cover EUAs that include substantially equivalent viral mutation Conditions of Authorization.

The New EUA Requirements

The revisions require test makers to take three steps to account for genetic variants:

1. Updated Labeling

FDA wants test makers to update their authorized labeling and submit it to the agency as a supplement to the EUA within three months. The letter includes a pair of Appendices setting forth detailed instructions. Appendix A requires test makers to add the following specific limitation language to their IFU/Laboratory SOP and/or EUA Summary:

> *The performance of this test was established based on the evaluation of a limited number of clinical specimens. Clinical performance has not been established with all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.*

Appendix B of the letter sets out limitation language that must be added to the Fact Sheet for Healthcare Providers, depending on the type of test:

Molecular and Antigen Tests: The following language must be added at the end of the section of the Fact Sheet titled "What does it mean if the specimen tests negative for the virus that causes COVID-19?":

> *The performance of this test was established based on the evaluation of a limited number of clinical specimens. The clinical performance has not been established in all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strainsof SARS-CoV-2 and their prevalence, which change over time.*

Continued on page 8

FDA Watch, Agency Tells EUA SARS-CoV-2 Test Makers to Account for Viral Mutations, *from page 7*

Serology Tests: The following paragraph must be added to the end of the Fact Sheet section called "What does it mean if the specimen tests negative for antibodies against virus that causes COVID-19?":

> *The performance of this test was established based on the evaluation of a limited number of clinical specimens. The clinical performance has not been established in allcirculating variants but is anticipated to be reflective of the prevalent variants incirculation at the time and location of the clinical evaluation. Performance at the time oftesting may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.*

2. Performance Evaluation

FDA is also requiring test makers to perform ongoing evaluation of SARS-CoV-2 viral mutations impact on test performance. Multianalyte test evaluation must address how mutations impact all analytes. Viral mutations that affect the expected performance of the test must be relayed to the agency by email, CDRH-EUA-Reporting@fda.hhs.gov).

3. Additional Labeling Updating

If requested by FDA, labeling must be updated within seven calendar days to include any additional labeling risk mitigations that the agency identifies regarding the impact of viral mutations on test performance.

In addition to the letter, FDA published a list of molecular tests whose performance could be impacted by viral mutations:

Molecular Tests Cited by FDA as Being Potentially Affected by Viral Mutations

Test Maker	Test
Mesa Biotech	Accula SARS-CoV-2 Test
Cepheid	Xpert Xpress SARS-CoV-2 test + Xpert Xpress SARS-CoV-2 DoD test + Xpert Omni SARS-CoV-2 test
Thermo Fisher Scientific	TaqPath COVID-19 Combo Kit
Applied DNA Sciences	Linea COVID-19 Assay Kit

FDA suggested that mutation impact on these tests "does not appear to be significant" for overall sensitivity and that it is providing the information "out of an abundance of caution."

● ● ●

Here are some of the key new FDA EUAs and clearances announced in September 2021:

New FDA Emergency Use Authorizations (EUAs) & Approvals (NEW)

Manufacturer(s)	Product
ANP Technologies	EUA for NIDS COVID-19 Antigen Rapid Test Kit
Northeastern University Life Sciences Testing Center	EUA for RT-PCR-based SARS-CoV-2 test
MolecuLight	510(k) clearance for MolecuLight i:X imaging device detecting wounds containing elevated levels of Pseudomonas aeruginosa
Paige	de novo marketing authorization for Paige Prostate
MeMed	510(k) clearance for MeMed BV test on MeMed Key platform
Takeda Pharmaceutical	Accelerated approval for mobocertinib (Exkivity) for previously treated, metastatic non-small cell lung cancers harboring EGFR exon20 insertion mutations
Quanterix	EUA for Simoa SARS-CoV-2 N protein antigen test expanded to include testing with saliva samples and for asymptomatic serial testing with nasal swab samples
Cairn Diagnostics	Expanded clearance for 13C-Spirulina Gastric Emptying Breath Test, or GEBT, to include at-home under virtual supervision
Cepheid	EUA for Xpert Xpress COV-2/Flu/RSV plus, a new version of its multiplex SARS-CoV-2, influenza, and respiratory syncytial virus test
Yale School of Public Health	EUA for SalivaDirect DTC Saliva Collection Kit and SalivaDirect test
Swiss Precision Diagnostics	Clearance for home-use Clearblue Early Digital Pregnancy Test
Atlas Link Technology	510(k) clearance for 3 over-the-counter pregnancy tests *Atlas One Step hCG Urine Pregnancy Test (Strip) *Atlas One Step hCG Urine Pregnancy Test (Cassette) *Atlas One Step hCG Urine Pregnancy Test (Midstream)
Abbott Laboratories	Clearance for use of i-Stat Chem8+ cartridge with i-Stat 1 System
Inova Diagnostics	510(k) clearance for Aptiva Celiac Disease IgG Reagents
Diazyme	Clearance for use of PLAC Test for Lp-PLA2 Activity on automated clinical chemistry analyzers
Ark Diagnostics	Clearance for Ark Lacosamide Assay
Ortho Clinical Diagnostics	Clearance for Vitros Chemistry Products PHBR Slides
Assure Tech	Clearance for AssureTech DOA Dipstick Screen Panel Tests
CD Diagnostics	Clearance for Synovasure Alpha Defensin Lateral Flow Test Kit
Manufacturer(s)	Product
Paige	de novo marketing authorization for Paige Prostate
MeMed	510(k) clearance for MeMed BV test on MeMed Key platform
Takeda Pharmaceutical	Accelerated approval for mobocertinib (Exkivity) for previously treated, metastatic non-small cell lung cancers harboring EGFR exon20 insertion mutations

Continued on page 10

FDA Watch, *from page 9*

Manufacturer(s)	Product
Quanterix	EUA for Simoa SARS-CoV-2 N protein antigen test expanded to include testing with saliva samples and for asymptomatic serial testing with nasal swab samples
Cairn Diagnostics	Expanded clearance for 13C-Spirulina Gastric Emptying Breath Test, or GEBT, to include at-home under virtual supervision
Cepheid	EUA for Xpert Xpress COV-2/Flu/RSV plus, a new version of its multiplex SARS-CoV-2, influenza, and respiratory syncytial virus test

New CE Marks & Global Certifications

Notable European CE certifications announced during the period:

NEW CE MARKINGS IN EUROPE

Manufacturer(s)	Product(s)
Zymo Research	EZ DNA Methylation-Lightning Kit
Zymo Research	SafeCollect line of sample collection kits
LGC SeraCare	AccuPlex SARS-CoV-2, Flu A/B, and RSV Reference Material Kit
Roche	PCR-based influenza A/B and respiratory syncytial virus test
Roche	PCR-based adenovirus, human metapneumovirus, and enterovirus/rhinovirus test
Roche	PCR-based parainfluenza 1, 2, 3, and 4 test
Microbio	InfectID-COVID-19 tests
DiaSorin Molecular	Simplexa COVID-19 & Flu A/B Direct test
Thermo Fisher Scientific	TaqPath COVID-19 RNase P 2.0 kit
Seegene	Use of its Combo Swab self-collection device with four of firm's SARS-CoV-2 molecular diagnostic assays

Other international clearances announced during the period:

Manufacturer(s)	Country(ies)	Product(s)
Thermo Fisher Scientific	Japan	Oncomine Dx Target Test as companion diagnostic to identify patients with RET-fusion positive non-small cell lung cancer (NSCLC) who may be candidates for treatment with Eli Lilly's selpercatinib
Co-Diagnostics said this week that CoSara Diagnostics (joint venture of Co-Diagnostics in India)	India	Saragene RT-PCR tests for dengue and chikungunya viruses

DX Deals: Twist Bioscience Unveils 3 New Strategic Collaborations for Synthetic Biology Discovery, *from page 1*

Now the South San Francisco-based company is aggressively pursuing strategic collaborations designed to expand its synthetic DNA manufacturing process, unveiling three new partnerships in the past six weeks.

The 3 Deals

The dealmaking spree began on Aug. 18, when Twist announced that it had partnered with reagent developer SomaLogic to discover new antibodies. The plan calls for Twist to identify antibodies against targets coming out of SomaLogic's SomaScan proteomics platform. "The SomaScanplatform provides a rich source of clinically relevant biomarkers in diverse therapeutic areas," noted Twist CEO and cofounder Emily Leproust in a statement. Twist will then move the antibodies discovered through its internal pipeline, with the most promising candidates to undergo preclinical development and subsequent outlicensing to a partner.

On Sept. 13, Twist announced a new collaboration with Menlo Park, California-based Adicet Bio to discover T-cell based cancer therapies for five undisclosed targets. Adicet produces off-the-shelf gamma delta T cells that can be used to enhance tumor targeting. Twist will provide its single-chain variable fragment and single-domain VHH antibody (nanobody) technologies to discover unique target-specific binders in exchange for an undisclosed upfront technology license fee for each program. Twist will also receive clinical and regulatory milestone payments and royalties for any product resulting from the selected targets.

The third deal, which was announced on Sept. 23, follows the same basic pattern but in the realm of artificial intelligence (AI). Twist's collaborator is DeepCDR, a company that uses deep learning algorithms to discover and optimize antibodies. Twist will utilize Switzerland-based DeepCDR's large panels of fully human antibody sequences to build multiple fully human naive synthetic antibody libraries, specifically, AI Hypermutated single-chain fragment variable (scFv) library and a new coronavirus-specific scFv library," Leproust noted in a statement.

● ● ●

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

Continued on page 12

DX Deals, *from page 11*

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS

Partner 1	Partner(s) 2+	Deal Summary
Beckman Coulter Life Sciences	Invitae	• Objective: Develop applications for Beckman's new next-generation sequencing library prep system • Dynamic: Invitae to create applications for Biomek NGenius Liquid Handling System available to instrument users via an electronic application library
Scienion	Pictor	• Objective: Commercialize a high throughput SARS-CoV-2 antibody testing system • Dynamic: Incorporate Scienion CL2 SciReader colorimetric microplate reader into Pictor's PictArray SARS-CoV-2 Serology Test to create platform capable of testing for both anti-nucleocapsid and anti-spike antibodies in one reaction
BostonGene	MD Anderson Cancer Center	• Objective: Validate and develop diagnostics based on cancer biomarkers identified by MD Anderson researchers • Dynamic: Expand existing collaboration to include investigator-sponsored retrospective and prospective studies to identify and validate biomarkers for different cancers
Genetic Technologies (GT)	Washington University's Institute for Public Health	• Objective: Expand predictive capability of GT's GeneType breast cancer risk assessment test for women of African descent • Dynamic: GT to fund 9-month study study analyzing over 1,000 samples over a nine-month period with 43.5 percent of study costs to be offset by R&D tax rebates
PathAI	Summit Clinical Research	• Objective: Launch clinical trial services solution for developers of nonalcoholic steatohepatitis (NASH) treatment drugs • Dynamic: Leverage PathAI's AI tools for liver pathology evaluation in combination with Summit's expertise in NASH drug development and accelerated study execution
Second Genome	Virginia Commonwealth University	• Objective: Discover a noninvasive stool-based biomarker for NASH • Dynamic: Apply Second Genome's machine learning-based sg-4sight discovery platform to patient samples provided by VCU to identify a composite biomarker to diagnose NASH patients with advanced fibrosis

Partner 1	Partner(s) 2+	Deal Summary
Persephone Biosciences	Janssen Biotech	• Objective: Use patient samples from Janssen clinical trial for biomarker discovery • Dynamic: Persephone to get access to stool samples obtained using its collection kit from patients in an undisclosed Janssen cancer clinical trial
Abacus Diagnostica	Kaivogen + Labrox	• Objective: Develop near-patient antibody and PCR tests for infectious diseases and cancers that can be run from a single device • Dynamic: Slated for 2024 launch, platform will leverage PCR technology and a single sample to identify more than 10 bacteria or viruses and determine if a patient's symptoms are caused by SARS-CoV-2, the flu or a cold
Helix	GenXys Health Care Systems	• Objective: Provide a clinical decision support solution for Helix's platform • Dynamic: Incorporate GenXys platform into electronic medical record systems of Helix's health system partners to serve as an "interpretation engine" for genetic test results
Genomenon	Alexion Pharmaceuticals	• Objective: Provide data to help genetic testing labs diagnose patients with rare diseases • Dynamic: Genomenon to use its AI-driven technology to create a "genomic landscape" for specific conditions
Molecular Health	Eone-Diagnomics Genome Center	• Objective: Create combined precision oncology test • Dynamic: Combine Molecular Health's MH Guide software and EDGC's OncoCatch-CDx assay • EDGC to utilize its analysis software for identifying genetic variants relevant for treating cancer patients to support reporting of OncoCatch-CDx results to ordering clinicians
Sebia	Metafora Biosystems	• Objective: Develop tests for Metafora's technology platform • Dynamic: Create new analytical methods, particularly in hematology, to support informed therapeutic decisions • Under partnership, Sebia's parent company Sphinx acquires minority share in Metafora

Continued on page 14

DX Deals, *from page 13*

Partner 1	Partner(s) 2+	Deal Summary
Deepcell	Stanford University	• Objective: Build out broad-scale human cell atlas • Dynamic: Deepcell to use its AI-based technology for label-free cell isolation and collection to help Stanford generate single-cell morphology data for the Tabula Sapiens program to build a benchmark human cell atlas of 2 million cells
Jumpcode Genomics	Translational Genomics Research Institute	• Objective: Support investigations into genomic epidemiology of SARS-CoV-2 • Dynamic: Use Jumpcode's CRISPRclean technology combining CRISPR-based technology with next-generation sequencing to deplete unwanted nucleic acid sequences from a sample, to increase sensitivity and efficiency of sequencing
Roche	Medial EarlySign	• Objective: Develop and commercialize AI-based early cancer detection tool • Dynamic: Clinical decision support tool will use EarlySign's software that incorporates lab results, EHR data and other clinical care, with initial focus on gastric cancer
Twist Bioscience	DeepCDR	• Objective: Use deep learning algorithms for antibody discovery and optimization • Dynamic: Latest in series of deals leveraging Twist's synthetic antibody phage display libraries for new antibody discovery
Twist Bioscience	Adicet Bio	• Objective: Develop T cell-based cancer therapies • Dynamic: Twist to use its single-chain variable fragment and single-domain VHH antibody (nanobody) technologies to discover unique target-specific binders for use in engineering immune cells with fully human chimeric antigen receptors and T-cell receptors directed to disease-specific cell surface antigens • Twist gets undisclosed upfront technology license fee for each program + clinical and regulatory milestone payments + royalties for any product resulting from selected targets

Partner 1	Partner(s) 2+	Deal Summary
SomaLogic	UPMC	• Objective: Find ways to use SomaLogic's proteomics platform to impact clinical care • Dynamic: Use SomaScan platform for clinical research and development projects exploring clinical uses of proteomic data, e.g., to inform doctors and patients about a person's real-time health status or disease risk
Cedars-Sinai Cancer	Tempus	• Objective: Advance a precision medicine research initiative • Dynamic: Molecular Twin project to create a database of information to guide oncology treatment strategies and inform new research • Collect patient samples and use them to create virtual replicas of their DNA, RNA, protein and other medical information
Siemens Healthineers	A1 Life Sciences	• Objective: Develop and commercialize PCR-based assays for identifying SARS-CoV-2 mutations and variants • Dynamic: Portfolio of A1 Life Sciences' Diagnovital kits to complement Siemens' FTD SARS-CoV-2 Assay for initial diagnosis of SARS-CoV-2 by allowing for determining if positive sample harbors a mutation or variant of concern • Siemens to distribute portfolio internationally for research use only
Foundation Medicine	Science 37	• Objective: Create a home-based clinical trial model for patients who can't travel to clinical trial sites • Dynamic: Foundation to use its FoundationSmartTrials patient identification tool to identify patients who may be eligible for a clinical trial based on results from company's comprehensive genomic profiling tests • Science 37 to enroll patients and provide ongoing support
Bio-Techne	Carterra	• Objective: Study more than 40 COVID-19 variants • Dynamic: Use Carterra's LSA high-throughput analytical platform to characterize panels of SARS-CoV-2 spike and receptor-binding domain variants to create tests for joint global launch in US, Europe and Asia

Continued on page 16

Dx Deals, *from page 15*

Partner 1	Partner(s) 2+	Deal Summary
Illumina	Merck	• Objective: Develop and commercialize tests gauging genetic mutations in homologous recombination deficiency (HRD) and identify best responders to PARP inhibitors • Dynamic: Illumina to develop new HRD companion diagnostic for EU and UK markets to help identify ovarian cancer patients eligible for treatment with olaparib (Lynparza), a PARP inhibitor jointly developed by Merck and AstraZeneca
Agilent Technologies	Visiopharm	• Objective: Comarket Agilent's automated pathology staining solutions with Visiopharm's AI-based pathology software products worldwide • Dynamic: Initial focus on Europe • Deal marks Agilent's entry into digital pathology

Click here to see the rest of the October deals