G2 INTELLIGENCE
A DIVISION OF PLAIN LANGUAGE MEDIA

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LABORATORY INDUSTRY REPORT™

Vol. 20, Iss. 7
July 2020

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G2Intelligence.com

Lab Market: Employers Show Signs of Hesitation on COVID-19 Return to Work Testing

Business reopening and return to work was expected to create a massive new market for employer point-of-care COVID-19 workplace screening tests. However, there are troubling new indications that employer demand for testing has been tempered due to concerns over test accuracy, supply and logistics and employee privacy rights. Exhibit A: A new survey showing that while the vast majority of employers nationwide are contemplating COVID-19 screening of employees, few have or plan to make it the central focus of their return-to-work program.

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Diagnostics Deals: Global Non-Profit & Smartphone DX Firm to Create Malaria Diagnosis App

Malaria continues to wreak havoc around the world, particularly in low- and middle-income countries (LMICs). Although rapid in vitro diagnostic tests (RDTs) for malaria are widely used in those countries, implementation of malaria RDTs has been linked, in cases with negative malaria results, to an increased use of antibiotics. Moreover, analysis of malaria RDT results is tricky and prone to a high rate of error by lab workers. But now a global non-profit and producer of smartphone-based, at-home diagnostics have embarked on a new project designed to remedy that problem.

The Partners

The Foundation for Innovative New Diagnostics (FIND) is a global non-profit organization that works with researchers,

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The Survey

The survey from law firm Littler compiles the results of an online COVID-19 Return to Work Survey completed by over 1,000 US corporate leaders and professionals between May 5 to 14, including:

- Human resources professionals (59%);
- General counsel/in-house attorneys (31%);
- C-suite executives and other professionals (10%).

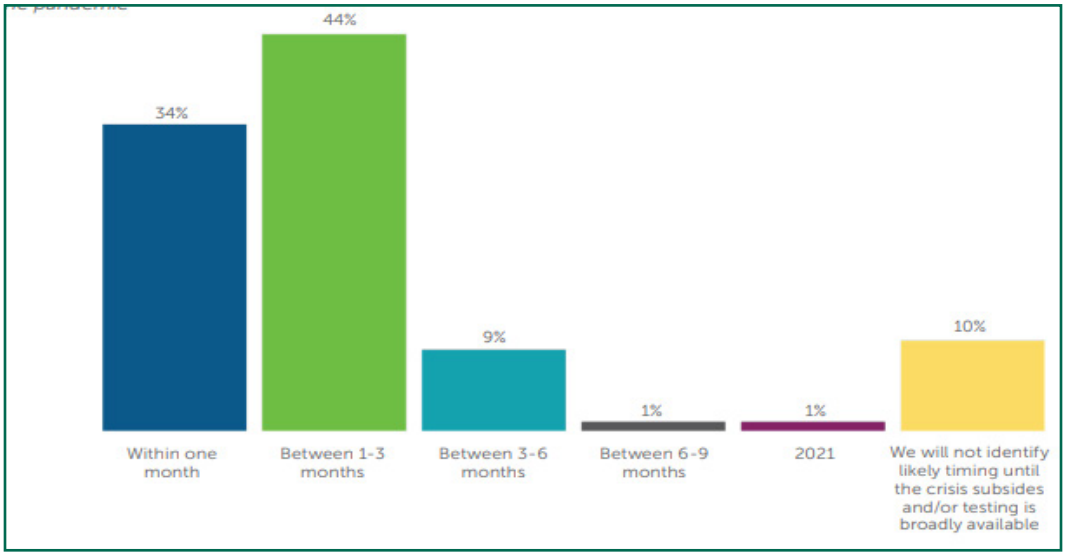
Respondents' companies represented a wide range of sizes:

- One to 100 employees (15%);
- 101 to 500 employees (28%);
- 501 to 1,000 employees (12%);
- 1,001 to 5,000 employees (22%);
- 5,001 to 10,000 employees (8%);
- More than 10,000 employees (14%).

Pace of Reopening

The first key finding is the cautious pace of reopening. Most employers say they've adopted a wait-and-see approach, with 42% saying they plan to monitor the outcome of other business reopening's before making their own decisions. Only 18% of respondents indicated that they plan to bring employees back immediately after each stay-at-home order is lifted. Another 33% say they'll wait a few weeks, and 10% they won't reopen at all until the crisis subsides and/or testing becomes broadly available.

Graph A: When Businesses Plan to Reopen after Stay-at-Home Order Is Lifted (Non-essential businesses only)



Source: Littler

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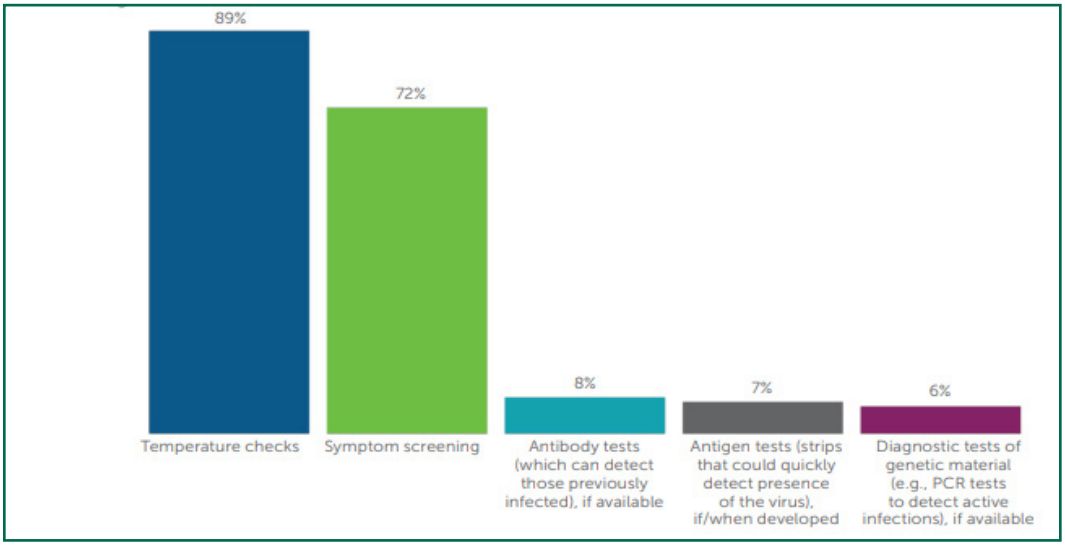
Laboratory Industry Report (ISSN 1060-5118) is published by G2 Intelligence, Plain Language Media, LLLP, 15 Shaw Street, New London, CT, 06320.
Phone: 888-729-2315
Fax: 855-649-1623
Web site: www.G2Intelligence.com.

The Role of Point-of-Care COVID-19 Testing

Health screening of some sort will be part of their return to work strategies for 58% of respondents—almost 70% of respondents at companies with over 5,000 employees. Among these, 89% indicated that they'll perform temperature checks, and 72% said that they'll do symptom screening. More than 80% of those respondents say screenings will be mandatory.

Graph B: Health Screening Methods Employers Plan to Use



Source: Littler

However, as shown by Graph B, COVID-19 testing figures to play a much less prominent role, cited by only 21% of companies planning to implement health screening. Among these, 8% of indicated they would conduct antibody testing, 7% said they'd conduct antigen testing and just 6% said they'd perform PCR or genetic tests.

Liability Concerns

Concerns over liability may explain the relatively low numbers of employers planning to perform COVID-19 testing on employees. The key concerns:

- **Privacy:** Test results are protected health information (PHI) that require consent to collect under HIPAA and other privacy laws; and
- **Disability Discrimination:** The performance of tests is a medical exam banned by the federal Americans with Disabilities Act (ADA) and state civil rights laws.

The good news is that both the federal Office for Civil Rights and US Equal Employment Opportunity Commission (EEOC) and equivalent state agencies have given the greenlight for testing as a temporary health and safety measure during the COVID-19 pandemic. However, that authorization doesn't cover serological antibody testing due to the

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inaccuracy of such tests. Thus, on June 17, the EEOC issued guidelines making it clear that employers may not make employees submit to antibody testing, citing CDC Interim Guidelines that these tests are inaccurate and "should not be used to make decisions about returning persons to the workplace."

Moreover, even in performing permitted molecular and antigen tests, employers must adhere to strict limitations to ensure they collect, use and disclose only the information necessary to accomplish the purpose of COVID-19 screening and keep test results confidential and secure. All of this is enough to give at least some employers the heebie-jeebies.

Case Studies: Some Companies Relying on COVID-19 Screening Tests

While there seems to be at least some hesitation on the use of employee COVID-19 testing, some companies are making testing a central focus of their return to work strategy. For example, Delta Airlines just launched a program to test employees for active COVID-19 and antibodies under a partnership with the Mayo Clinic and Quest Diagnostics Inc. Chief Executive Ed Bastian in an employee memo said the program would "evolve into a full testing protocol – something that will be essential as we ... begin the return to normal operations." Delta's testing program was rolled out in Minneapolis, followed by Atlanta, Detroit and New York.

Yale University also launched a free and voluntarily pilot COVID-19 screening program to nearly 6,000 members of faculty, staff, and trainees who were currently authorized to be on campus or returning as part of phase one of research reactivation. As of the end of the first week, over 1,000 tests were completed for enrollees.

Key Lab Players in Return to Work Testing Segment

Lab companies that have invested heavily in employer return to work COVID-19 screening testing and services space include:

- **LabCorp**, which on May 14 launched LabCorp Employer Services offering customized return to work solutions using trained medical staff for employee check-in health questionnaires, temperature screens and COVID-19 test collection at the employer site or offsite. The service includes the firm's new at-home collection test kit, fingerstick antibody blood test and (starting this fall) flu vaccine services.
- **Quest**, which on May 27 launched its Quest Diagnostics Return to Work services suite, including on-site temperature checks, respiratory and blood specimen collection, online questionnaires, access to telemedicine services and contract tracing initially targeting healthcare workers, first responders and other high-risk jobs involved in pandemic response.

- **ChristianaCare**, one of the largest healthcare providers in the mid-Atlantic region provider which on June 8, launched a telehealth Employee COVID-19 Symptom Monitoring and Testing Program that has so far signed up 12 Delaware employers covering about 5,000 employees.
- **Verily**, an Alphabet company, which on June 18 launched its Healthy at Work program combining symptom screening, testing services, and data analytics. The initiative comes on the heels of Verily's Baseline COVID-19 Testing Program which has tested more than 220,000 individuals across 13 states in partnership with state and local public health authorities.

Takeaway

Even worse news for labs involved in on-site COVID-19 return to work testing came on June 23 when the Trump administration clarified that, unlike tests ordered by medical providers for coronavirus diagnosis and treatment, insurers would not be obligated to pay for employer screening tests. (See the related story on **page 5***) The policy is likely to have only a marginal effect on Quest, LabCorp and other labs providing testing for healthcare, skilled nursing and other high-risk, essential workers for whom screening testing is mandatory under state or local law. But loss of the insurance safety net is likely to discourage at least some non-essential employers to take a pass on preventive COVID-19 return to work screening.*

Reimbursement: Feds Say Insurers Not Required to Pay for Employer Return to Work COVID-19 Testing

Since the public health emergency began, the US government has taken the position that insurers shouldn't be allowed to make consumers pay for COVID-19 lab tests. But now comes news that insurers will not be put in that same position with regard to return to work screening conducted on employees by their employers. And while the plan is for employers to pay for that testing, labs that perform COVID-19 screening tests may get left holding the bag.

FFCRA Rules for COVID-19 Test Payment

The key piece of federal relief legislation, the Families First Coronavirus Response Act (FFCRA), required insurers to cover COVID-19 tests without imposing any copayments, deductibles, coinsurance or other patient cost-sharing. But the rule (Section 6001 of FFCRA) rule applied only to tests deemed "medically appropriate" by a healthcare provider. The key

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Reimbursement: Feds Say Insurers Not Required to Pay for Employer Return to Work COVID-19 Testing, *from page 5*

question: Would insurers also have to foot the bill for screening tests not used for diagnosis and treatment?

Apparently, the answer is no. On June 23, the Department of Labor, HHS and Treasury issued joint guidance (FAQ 5) clarifying that Section 6001 doesn't apply to "testing conducted to screen for general workplace health and safety (such as employee "return to work" programs, for public surveillance or any other purpose not primarily intended for individualized diagnosis or treatment of COVID-19."

Takeaway: Significance for Labs

So, if insurers aren't on the hook, the consumers, i.e., employers will have to pay for return to work screening. Of course, this may discourage many employers from offering such testing in the first place—other than employers in skilled nursing and other high-risk facilities in which screening testing is mandated by state or local law.

As with the original Section 6001 rule, labs may once more get caught in the middle and end up having to pay at least some of the cost. "While there is widespread agreement that this testing is necessary, the issue of how these tests will be paid for remains unclear," American Clinical Laboratories Association President ***Julie Khani*** *in a written statement. "Laboratories cannot — and should not be expected to — absorb the costs for return to work and surveillance testing."*

FDA WATCH

First Warning Letters Issued for Improper Marketing of SARS-CoV-2 Antibody Tests

No more Mr. Nice Guy. For the first time, the FDA has exercised its enforcement powers to crack down on makers of unproven serologic SARS-CoV-2 antibody tests.

A 180 Pivot

When the public health emergency first began, the FDA allowed producers to introduce antibody tests immediately upon self-validation without Emergency Use Authorization (EUA) via its newly created "Policy D" pathway. Predictably, the US market was soon awash with unproven tests deceptively touted as having FDA approval. The agency sounded the alarm and called on test makers to submit their products to federal labs for independent evaluation. Few did.

The turning point came in early May when, in response to a scathing Congressional investigational report, the FDA put its foot down,

ending Policy D and making independent evaluation mandatory for all SARS-CoV-2 antibody tests, including those with EUA. Less than two weeks later, nearly 30 Policy D tests were either delisted or voluntarily withdrawn by their manufacturers.

On June 16, the agency revoked the EUA of one of the first serologic SARS-CoV-2 antibody tests to receive authorization, Chembio Diagnostic's DPP COVID-19 IgM/IgG test, citing concerns about its sensitivity and specificity. According to the agency, Chembio and independent laboratory evaluation data showed that the test "generates a higher than expected rate of false results and higher than that reflected in the authorized labeling for the device."

The Warning Letters

Even so, while the FDA had threatened, it did not actually initiate any enforcement actions. But that changed on June 17, the agency announced that it had issued three warning letters to companies for improper marketing of SARS-CoV-2 antibody tests:

- Medakit, which is based in Hong Kong;
- Antibodiescheck.com and Yama Group in the United Arab Emirates; and
- Chicago-based Jason Korkus and Sonrisa Family Dental, doing business as www.mycovidtest19.com.

The FDA claims the companies were selling tests directly to consumers for at-home use without proper regulatory clearance, approval, or authorization. Among the tests that were improperly marketed, one actually has received EUA, namely, the Cellex Test Kit from Cellex which is sold by Sonrisa. However, the EUA for the test covers only labs certified to perform moderate- and high-complexity tests under CLIA.

The agency asked the three firms to immediately correct the violations, including stopping the sale of the products or preventing future sales, or face possible legal action, such as seizure and injunction.

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In addition to the following clearances announced in late May and June, the FDA expanded the Fulgent Genetics' SARS-CoV-2 test EUA to include consumer-initiated testing with the COVID-19 Home Collection Kit offered by Fulgent's consumer-facing Picture Genetics subsidiary:

New FDA Emergency Use Authorizations (EUAs) & Approvals

Manufacturer(s)	Product
Illumina	EUA for Illumina COVIDSeq Test, first NGS test to get EUA for detecting SARS-CoV-2

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FDA Watch, *from page 7*

Manufacturer(s)	Product
Roche	Clearance for Cobas EZH2 Mutation Test as companion diagnostic for Epizyme's tazemetostat (Tazverik) for relapsed follicular lymphoma patients with EZH2 mutation
Roche	EUA for Elecsys IL-6 test to identify severe inflammatory response in COVID-19 patients
Foundation Medicine	Clearance for FoundationOne CDx as a companion test for Merck's Keytruda (pembrolizumab)
Emory University	EUA for SARS-CoV-2 RBD IgG ELISA-based serologic test
Kaiser Permanente	EUA for KPMAS COVID-19 Test + home collection kit
Applied BioCode	EUA for SARS-CoV-2 Assay
Quidel	Amended EUA to run Sofia SARS Antigen FIA on Sofia Fluorescent Immunoassay Analyzer
RTA Laboratories	EUA for Diagnovital SARS-CoV-2 Real-Time PCR Kit
Cormeum Laboratory Services	EUA for SARS-CoV-2 assay detecting N, S + Ofr1ab regions in virus' genome
Cue Health	EUA for Cue COVID-19 Test
Tide Laboratories	EUA for DTPM COVID-19 RT-PCR test
TBG Biotechnology	EUA for ExProbe SARS-CoV-2 Testing Kit
ChromaCode	EUA for announced Wednesday HDPCR SARS-CoV-2 Real-Time PCR assay
Siemens Healthineers	EUA for Dimension Vista SARS-CoV-2 total antibody assay + Dimension EXL SARS-CoV-2 total antibody assay
Euroimmun	EUA for EuroRealTime SARS-CoV-2 molecular assay
Phosphorus Diagnostics + Genetron Health	EUA for COVID-19 RT-qPCR Test detecting SARS-CoV-2 RNA in saliva specimens collected by providers or patients at home
Quest	EUA for Self-collection Kit for COVID-19
3B Blackbio	EUA for Biotech India COVID-19 test
Bioperfectus Technologies	EUA for COVID-19 Coronavirus Real Time PCR Kit to detect SARS-CoV-2 ORF1ab and N genes
Omnipathology Solutions	EUA for Omni COVID-19 ASSAY by RT-PCR
Biohit Healthcare	EUA for SARS-CoV-2 IgM/IgG Antibody Test Kit
ADS Biotec	EUA for SARS-CoV-2 Antibody Detection Kit
Ohio State University	EUA for OSUWMC COVID-19 RT-PCR test
Thermo Fisher Scientific	Breakthrough Device Designation for Oncomine Precision Assay to identify low-grade glioma patients with isocitrate dehydrogenase 1 and 2 mutations eligible for treatment with vorasidenib

New CE Marks & Global Certifications

Notable European CE certifications announced during the period:

NEW CE MARKINGS IN EUROPE

Manufacturer(s)	Product(s)
R-Biopharm	Rida Gene SARS-CoV-2 test
Beckman Coulter	Access SARS-CoV-2 IgG antibody test
DiaSorin Molecular	Simplexa Congenital CMV Direct kit for detection of cytomegalovirus (CMV) DNA
NeuMoDx Molecular	PCR-based NeuMoDx HIV-1 assay
Yourgene Health	Iona Nx NIPT Workflow to run on Illumina's NextSeq 550Dx NGS platform
PerkinElmer	Delfia Xpress sFlt-1 kit for predicting preeclampsia
Promega	OncoMate MSI Dx Analysis System
QuantuMDx	Opti SARS-CoV-2 RT-PCR kit
Opti Medical Systems	DeepChek sequencing-based assays for HIV genotyping and drug resistance testing
Eurofins Technologies	Ingezim COVID 19 DR total antibody assay for indirect diagnosis of past exposure to SARS-CoV-2
MeMed	MeMed BV diagnostic test and MeMed Key point-of-care platform
Mobidiag	Novodiag COVID-19 and Amplidiag COVID-19 PCR tests

Other international clearances announced during the period:

Manufacturer(s)	Country(ies)	Product(s)
Sysmex	Japan	Ministry of Health, Labour, and Welfare approval for use of saliva with BGI Genomics' 2019-nCoV Fluorescence Detection Real-Time RT-PCR Kit

M&A Report: Invitae-ArcherDX Merger to Create Precision Oncology Powerhouse

While M&A deal volume remains abnormally low, business is expected to pick up this summer as the reopening process gets into high gear. Meanwhile, a few new deals are being made, including transactions of major strategic significance.

Invitae to Merge with ArcherDX

In one of the year's most significant deals, Invitae announced on June

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

22 that it plans to acquire fellow cancer genetics firm ArcherDX for $1.4 billion, including $325 million in cash, 30 million shares of Invitae common stock upfront and 27 million more shares later upon the achievement of certain milestones.

The Financing:

To finance the deal, Invitae plans to sell $275 million in common stock, $16.85 per share, in a private placement. The firm has also entered into a credit facility of up to $200 million with Perceptive Credit Opportunities Funds.

The Strategy:

Already a leader in genetic testing to assess hereditary cancer risk, Invitae will bolster its tumor profiling services and liquid biopsy technology by acquiring ArcherDX's precision oncology assets, including its Stratafide pan-cancer test for identifying actionable genomic alterations from blood and tissue samples and Personalized Cancer Monitoring platform to assess the progress of cancer treatment and detect early signs of recurrence.

"From the beginning, Invitae's goal has been to aggregate the world's genetic tests into a single platform in service of our mission to bring comprehensive genetic information into mainstream medicine," noted Invitae CEO **Sean George** in a statement. In his own statement, ArcherDX CEO **Jason Myers** said that the firm's products can help bring precision oncology into regional and community settings, where the majority of cancer patients receive care, and address an estimated $45 billion market opportunity.

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

MERGERS, ACQUISITIONS & ASSET SALES

Acquiring Company	Target(s)	Deal Summary
Invitae	ArcherDX	• Price: $1.4 billion, including $325 million cash + 30 million shares of Invitae common stock + additional 27 million shares contingent on achieving milestones • Status: Merger agreement signed but no closing date announced • Merger enables Invitae to add ArcherDX's Invitae tumor profiling and liquid biopsy technologies + services

Acquiring Company	Target(s)	Deal Summary
Illumina	BlueBee	• Price: Undisclosed • Status: Closed • Acquisition of Netherlands-based bioinformatics firm boosts Illumina's cloud-based genomic analysis capabilities
Foundation Medicine	Lexent Bio	• Price: Undisclosed • Status: Closed • Acquisition of precision oncology firm enables Foundation Medicine expand its liquid biopsy platforms and advance cancer care
OncBioMune Pharmaceuticals	Avant Diagnostics	• Price: OncBioMune issued shares of its Series D-1 convertible preferred stock, which will convert to 4.4 billion shares of common stock; OncBioMune also raised $1.08 million in Series C-2 convertible preferred stock in a private placement • Status: Closed • Molecular profiling company to be renamed Theralink Technologies
Medix Biochemica	EastCoast Bio	• Price: Undisclosed • Status: Closed • Acquisition of antigens, antibodies, and blocking buffers producer expands Medix's antibody and antigen offering in drugs of abuse, infectious disease and veterinary testing
OraSure Technologies	UrSure	• Price: $3 million cash + up to $28 million in post-closing contingent payments • Status: No closing date given • Acquisition of company that develops products measuring adherence to HIV medications

Diagnostics Deals: Global Non-Profit & Smartphone DX Firm to Create Malaria Diagnosis App, *from page 1*

DX companies and regulators to facilitate the creation and distribution of diagnostics tools targeting six areas of major disease in LMICs.

Los Angeles-based Scanwell Health creates smartphone-enabled, at-home diagnostics for acute illnesses, chronic diseases and rare conditions, including the first and only over-the-counter app for urinary tract infection testing and treatment cleared by the FDA. The firm is also awaiting emergency use authorization from the FDA for an at-home SARS-CoV-2 test based on proprietary technology for interpreting lateral flow results.

The Partnership

The objective of the partnership, which was signed last in 2019, is to develop a smartphone app that uses machine learning and computer vision algorithms to read RDTs for malaria that healthcare professionals in those countries can use to interpret and record test results easily and more accurately to identify the specific malaria strain and determine the appropriate treatment. Based on the same lateral-flow test technology used by the Scanwell at-home SARS-CoV-2 test, the malaria app will be compatible with multiple RDT and mobile device brands and types, and thus suitable for broad use in LMICs.

The Scanwell app will also support on-the-ground data collection and feed into regional and national digital surveillance systems designed to help combat antimicrobial resistance (AMR). AMR, which undermines the efficacy of antibiotics, is of disproportionately greater concern in LMICs, where health systems tend to be weak, resources are often in short supply and "just in case" prescribing of antibiotics is common.

The partners expect to complete evaluation of the app and make it available in at least two to three LMICs this year. The implementation will focus on connecting this app with existing digital tools at a community healthcare level and national surveillance systems for monitoring AMR.

The End Game

"Malaria elimination and robust disease surveillance both depend on point-of-care testing that can be performed at the lowest levels of the healthcare system," noted FIND CEO **Catharina Boehme**, CEO of FIND. "Using technology to optimize the use of RDTs for better patient care, while also enabling the collection of critical data to inform policy decisions on AMR strategies—and potentially also pandemic response—is a double win."

• • •

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

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS

Partner 1	Partner(s) 2+	Deal Summary
Thermo Fisher Scientific	Daiichi Sankyo	• Objective: Develop companion diagnostic for patients with non-small cell lung cancer (NSCLC) • Dynamic: Assay to use Thermo Fisher's Oncomine Dx Target sequencing test to identify NSCLC patients with mutations in HER2 who may be eligible for treatment with Enhertu (DS-8201), a HER2-directed antibody-drug-conjugate that Daiichi is developing
Thermo Fisher Scientific	Genetron Health	• Objective: Commercialize next-generation sequencing-based (NGS) diagnostics in China • Dynamic: Bring Genetron S5, which is based on Thermo Fisher's Ion GeneStudio S5 instrument for targeted NGS, to China public hospitals for cancer diagnostics, genetic disease diagnosis, microbial testing and reproductive health testing
Thermo Fisher Scientific	Agios Pharmaceuticals	• Objective: Codevelop companion diagnostic test to identify low-grade glioma patients with IDH1 and IDH2 mutations eligible for Agios' investigational inhibitor vorasidenib • Dynamic: Expand current collaboration with Thermo Fisher to retain global commercialization rights to commercialize the test globally and take lead in seeking regulatory clearances
NuProbe	Weigao Group	• Objective: Develop liquid biopsy NGS panel for NSCLC for Chinese market • Dynamic: Leverage NuProbe's blocker displacement amplification (BDA) technology to create product compatible with available desktop NGS instruments, and competitive in terms of sensitivity
ArcherDx	Bristol Myers Squibb	• Objective: Use ArcherDx's personalized cancer monitoring (PCM) assays for minimal residual disease (MRD) detection in cancer patients treated with immunotherapy • Dynamic: Evaluate clinical samples from cancer-patient cohorts to advance MRD detection or ctDNA clearance to potentially inform future therapy selection and/or optimization

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Diagnostics Deals, *from page 13*

Partner 1	Partner(s) 2+	Deal Summary
ArcherDx	AstraZeneca	• Objective: Develop assays to detect MRD in early-stage NSCLC patients • Dynamic: ArcherDx to perform exome sequencing of samples and generate patient-specific, research-use-only circulating tumor DNA assays for use in AstraZeneca's new Phase III MERMAID-1 trial evaluating effect of adjuvant treatment with durvalumab (Imfinzi) plus chemotherapy versus chemotherapy alone on disease-free survival
Canopy Biosciences	OnRamp Bioinformatics	• Objective: Offer OnRamp's Rosalind cloud-based genomic informatic platform to contract research organizations using Canopy's gene expression services • Dynamic: Expansion of current partnership enabling Canopy customers to use Rosalind to visualize differential gene expression data from NanoString and RNA sequencing files, even if they lack other bioinformatics capabilities
SpeeDx	Roche	• Objective: Expand global access to SpeeDx's infectious disease and antibiotic resistance tests • Dynamic: Non-exclusive agreement giving Roche access to SpeeDx's tests and technology, including new ones for managing antibiotic resistance in sexually transmitted infections
Dante Labs	Cambridge Cancer Genomics + Nonacus	• Objective: Develop high-throughput cancer sequencing and interpretation service for tumor profiling • Dynamic: Service to combine Dante Labs' experience in sequencing services for solid tumor and cell-free circulating tumor DNA from liquid biopsies with Nonacus' targeted pan-cancer NGS libraries and CCG.ai's AI-based software platform, OncOS
Foundation for Innovative New Diagnostics	Scanwell Health	• Objective: Develop smartphone app to interpret rapid malaria diagnostic tests • Dynamic: Use Scanwell technology using machine learning and computer vision algorithms to read rapid in vitro diagnostic tests for an app compatible with many types of mobile devices and tests
Twist Bioscience	Serimmune	• Objective: Identify and evaluate antibody candidates for SARS-CoV-2 therapy • Dynamic: Evaluate existing Twist antiboides using Serimmune's Serum Epitope Repertoire Analysis platform

Partner 1	Partner(s) 2+	Deal Summary
MilliporeSigma	10x Genomics	• Objective: Develop single-cell CRISPR screening workflows • Dynamic: Workflows to combine MilliporeSigma's CRISPR genome editing reagents with 10x's Feature Barcode assay to enable single-cell screens for changes in gene expression
Avalon GloboCare	GensKey Medical Technology	• Objective: Commercialize point-of-care antibody and PCR tests for SARS-CoV-2 • Dynamic: Both tests have received CE-IVD marking and awaiting FDA Emergency Use Authorization (EUA)
Sherlock Biosciences	Integrated DNA Technologies	• Objective: Manufacture Sherlock's CRISPR SARS-CoV-2 testing kits on large scale • Dynamic: Kit, the first CRISPR-based diagnostic test to receive EUA for SARS-CoV-2 detection, provides specific and sensitive detection of virus in patient samples without need for specialized instruments
Life Science Biosensor Diagnostics (iQX subsidiary)	Harvard University's Wyss Institute for Biologically Inspired Engineering	• Objective: Develop SARS-CoV-2 antibody test • Dynamic: Conductpilot study to integrate LSBD's Biosensor platform with an assay system developed by Wyss Institute to detect IgM or IgG antibodies against SARS-CoV-2
Prescient Metabiomics	Harvard's TH Chan School of Public Health	• Objective: Investigate microbiome biomarkers in colon cancer • Dynamic: Study use of microbial biomarkers to identify precancerous adenomas and carcinomas in the colon
Takara Bio USA	BioSyntagma	• Objective: Develop and validate a high-throughput SARS-CoV-2 detection method • Dynamic: Method uses Takara Bio's SmartChip PCR instrument, chips and reagents to run 5,184 reactions per chip in less than 30 minutes of direct hands-on time
Swift Biosciences	Arbor Biosciences (division of Chiral Technologies)	• Objective: Provide complete workflow for RNA-seq library preparation and targeted enrichment of SARS-CoV-2 genome • Dynamic: Combine Swift's patented Adaptase technology and RNA library kits with Arbor's myBaits technology for hybridization-based target enrichment of virus for whole-genome sequencing

Continued on page 16

Diagnostics Deals, *from page 15*

Partner 1	Partner(s) 2+	Deal Summary
Codexis	Alphazyme	• Objective: Produce and comarket enzymes for life science and diagnostic applications • Dynamic: Alphazyme to be exclusive manufacturer of three Codexis-developed enzymes • Alphazyme also gets comarketing rights to certain Codexis enzymes
Illumina	Genomic Medicine Sweden	• Objective: Assess whether whole-genome sequencing and RNA sequencing can replace conventional first-line clinical diagnostic methods for acute leukemia • Dynamic: Conduct nationwide study of about 450 patients
BioGX	Bosch Healthcare Solutions	• Objective: Develop point-of-care infectious disease tests for Bosch's Vivalytic platform • Dynamic: BioGX to develop, manufacture + supply reagents for Vivalytic cartridges and provide custom reagent manufacturing services for Vivalytic open system users

DISTRIBUTION, SALES & MARKETING AGREEMENTS

Product Owner	Distributor	Deal Summary
Lunaphore Technologies	Epredia	• Products: LabSat Research platform for rapid immunohistochemistry and immunofluorescence • Territory: US, UK, Germany • Non-exclusive • Distribution to begin in Japan in 2021
NLC Pharma	Todos Medical	• Products: NLC Pharma's 3C protease diagnostic platform for SARS-CoV-2 • Territory: Israel • Exclusive
Healgen Scientific	Menarini Silicon Biosystems	• Products: Healgen's COVID-19 IgG/IgM Rapid Test Cassette antibody detection kit • Territory: US • Non-exclusive
Sienna Cancer Diagnostics	Triolab	• Products: Sienna's hTERT bladder cancer test • Territory: Sweden • Exclusive

Product Owner	Distributor	Deal Summary
MedMira	Webb Diagnostic Technologies	• Products: MedMira's RevealCOVID-19 Total Antibody Test • Territory: Canada • Webb Diagnostic has placed initial order worth about $2.5 million

LICENSES

Licensor	Licensee	Deal Summary
St. Jude Children's Research Hospital	BioSkryb	BioSkryb acquires exclusive rights to use diagnostic test to detect and define populations of cancer cells during treatment
Ohio State Innovation Foundation	Exagen	Exagen gets exclusive worldwide license agreement to develop and market fibromyalgia blood test created by Ohio State
University of Illinois at Urbana-Champaign	Modular Bioscience	Modular gets exclusive global patent license to an artificial restriction enzyme (ARE) platform developed by the University
Rice University	NuProbe	NuProbe gets exclusive global license to two oligonucleotide technologies developed by Rice

SUPPLY, SERVICE & TESTING AGREEMENTS

Supplier/Servicer	Client/User	Deal Summary
GenMark Diagnostics	Vidant Health	Quotient to be Vidant Health's primary provider of rapid testing for SARS-CoV-2 and other infections

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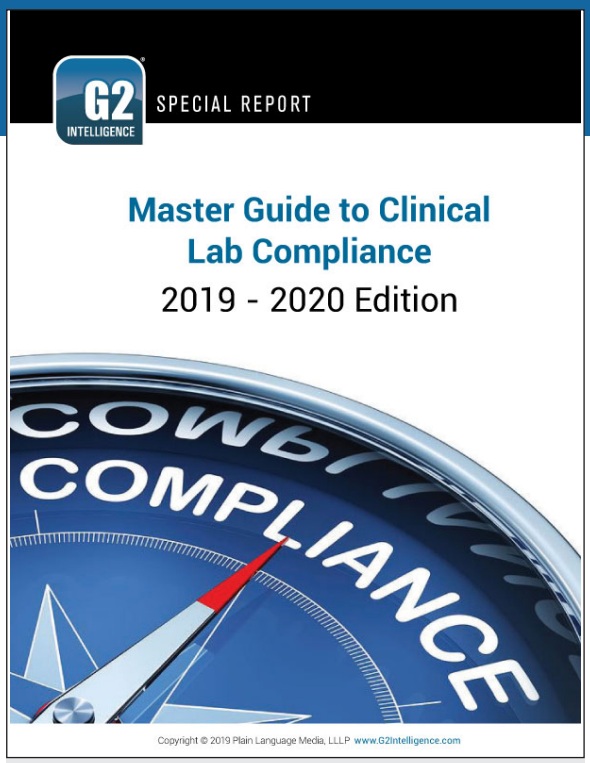

Lab Compliance Essentials **covers:**

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- Contract Sales Agreements
- Registry Payments
- Lab/Physician Relationships
- Gifts
- **And Much More!**

A Practical, Plain-Language Guide to Protecting Your Lab against Costly False-Claims, Anti-Kickback, and Stark Law Violations

For over two decades, clinical labs have been the target of a relentless stream of **investigations, audits, reviews, lawsuits**—and even **criminal prosecutions**—by the Centers for Medicare and Medicaid Services, and other Federal and State agencies.

Without a doubt, enforcement actions for **False-Claims violations** top the list. But the government has also systematically and aggressively grown the number of investigations into **Anti-Kickback** and **Stark Law violations.**

And that's just the tip of the iceberg. Investigations and **enforcement actions by state governments** have become increasingly aggressive... **whistleblower lawsuits** continue to grow sharply... and the ACA has earmarked **over $350 Million in funds for stepped up enforcement though 2020**, so you can be sure that labs like yours will come under increasing legal scrutiny.

Lab Compliance Essentials gives you the **practical, plain-language help** you need to understand the laws, and take **proven steps to protect your lab** from costly False-Claims, Anti-Kickback, Stark Law, and other legal and compliance violations.

For more information, please visit our website at **G2Intelligence.com/shop**

Or contact Andrea: **888-729-2315**, **Andrea@plainlanguagemedia.com**