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Inside the Lab Industry: Abbott and Quidel Stake Out Early Claims for Leadership of SARS-CoV-2 Rapid Antigen Testing Market

What COVID-19 antigen assays lack in accuracy with regard to RT-PCR testing is offset by their speed, low cost and scalability. In the long term, these advantages make point-of-care COVID-19 antigen testing a potential 9-, 10- or even 11-figure opportunity in the years to come. And now two of the industry's biggest companies have staked their claims to lead that market. Here's a look at what appears to be shaping up as a massive rivalry between Abbott Laboratories and Quidel for control of COVID-19 antigen testing.

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Emerging Tests: New Collaboration Seeks to Develop Handheld Breathalyzer Test for COVID-19

A handheld, easy-to-use breathalyzer device capable of accurately detecting COVID-19 at the point of care would represent a major 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 established to perform a massive clinical trial to test the idea. Here's the lowdown:

The Current COVID-19 DX Test Market

All agree that rapid and accurate point-of-care testing performed on a mass basis, including both the symptomatic and asymptomatic, is crucial to containing the spread of COVID-19. However, only a few of the COVID-19 diagnostic tests that have hit the market since the pandemic began have

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Inside the Lab Industry: Abbott and Quidel Stake Out Early Claims for Leadership of SARS-CoV-2 Rapid Antigen Testing Market, *from page 1*

The Promise of Antigen Testing

Testing the symptomatic is currently the immediate priority. But once case rates decline, the long term and sustainable opportunity created by the pandemic is the need for rapid point of care tests that can deliver accurate results at cost-effective prices for use in screening asymptomatic populations. RT PCR molecular tests performed at an offsite lab aren't suited to meet this need. Blood-based serology tests that detect SARS-CoV-2 antibodies are better suited for widespread and rapid screening, but lack the specificity and sensitivity of RT PCR assays.

Antigen tests that detect viruses indirectly—by identifying the presence of antigens or toxins a virus produces—are relatively inexpensive to produce and generate results rapidly at the point of care. And while its relative lack of sensitivity creates the risk of false negatives and need for confirmatory testing, antigen testing may still be appropriate for applications like screening health care workers and other high-risk groups and triaging patients during peak outbreak periods.

Industry Response: Quidel Strikes First but Abbott Strikes Back

Developers and manufacturers of rapid antigen tests have declared that they're ready, willing and able to meet this demand for increased testing. On May 8, the FDA granted the first Emergency Use Authorization (EUA) for a SARS-CoV-2 antigen test to Quidel's Sofia 2 SARS Antigen FIA rapid point-of-care test run on the firm's Sofia 2 analyzer.

On Aug. 26, Abbott upped the ante by securing EUA for its own SARS-CoV-2 antigen test, BinaxNow COVID-19 Ag Card providing test results readable *without* the use of an analyzer. The $5 test provides results in 15 minutes from a nasal swab that's twirled on a test card with a testing reagent added. The results can be read directly from the card, like a pregnancy test, with one line indicating a negative result and two lines indicating a positive result.

On Dec. 16, Abbott consolidated its advantage by announcing that the FDA expanded EUA for BinaxNow for virtually guided at-home use. Costing $25 and delivering results in 15 minutes, the BinaxNow uses a digital health platform from telehealth company eMed to facilitate delivery of the test to homes and guide the collection and testing process, as well as Abbott's own Navica app to display test results. Abbott indicated that it expects to deliver and administer 30 million tests in the first quarter of 2021, ramping up to 90 million in Q2.

Just two days later, Quidel secured EUA for its own readerless test, the QuickVue SARS Antigen test that delivers point-of-care results within 10 minutes via display of a colored line like a pregnancy test. Quidel said that

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it expects to ramp up QuickVue manufacturing to 600 million tests per year by the end of 2021.

Takeaway

Although SARS-CoV-2 point-of-care antigen testing is still in its formative stages, BinaxNow and QuickVue have emerged as the chief rivals—the Coke and Pepsi of the market. Both offer rapid results without the use of an analyzer. It's unclear which test enjoys the edge in accuracy. Quidel says that QuickVue has a sensitivity value of 96.6 percent and a specificity of 99.3 percent based on 194 test samples. These results are pretty much in line with the 97.1 percent sensitivity and 98.5 specificity Abbott initially reported for BinaxNow. However, those results were based on just 102 samples. After Abbott expanded the study to 460 samples, sensitivity fell to 84.6 percent and specificity remained at 98.5 percent.

FDA WATCH

Agency Greenlights First Over-the-Counter, At-Home COVID-19 Testing Kit

Nearly 250 COVID-19 diagnostic tests have gotten Emergency Use Authorization (EUA) from the FDA since the pandemic started. Almost all of them have been prescription products. In addition, 25 test kits have been cleared for home collection of samples. One of these products, Lucira Health's COVID-19 All-in-One Test Kit which received EUA on Nov. 17, is an all-in-one COVID-19 diagnostic enabling people to test themselves in their own home. But even that product requires a prescription. On Dec. 15, the FDA took things to the next level by greenlighting a full at-home COVID-19 testing kit that can be sold over the counter.

The Ellume COVID-19 Home Test

The OTC product that broke this new ground is the Ellume COVID-19 Home Test, a rapid antigen test capable of detecting fragments of the SARS-CoV-2 virus. Although the assay is performed on samples taken from nasal swabs, it's a Nasal mid-turbinate (NMT) test, which makes it less invasive than tests performed on samples taken using the much longer Nasopharyngeal (NP) swabs that require a trained a health care provider to administer.

More significantly, it's an over-the-counter rather than a prescription test. Accordingly, FDA Commissioner **Stephen M. Hahn**, MD, hailed

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FDA Watch: Agency Greenlights First Over-the-Counter, At-Home COVID-19 Testing Kit, *from page 3*

the approval as "a major milestone" in COVID-19 testing. "By authorizing a test for over-the-counter use, the FDA allows it to be sold in places like drug stores, where a patient can buy it, swab their nose, run the test, and find out their results in as little as 20 minutes," Hahn suggests.

Costing about $30, the Ellume test kit includes a sterile nasal swab, dropper, processing fluid, and a Bluetooth-connected "Analyzer," that pairs with an app providing step-by-step video instructions that users can upload to their smartphone. After the sample is analyzed, results are delivered to the user's smartphone via Bluetooth in 15 minutes or less.

The test is pretty accurate, having correctly identified 96 percent of positive samples and 100 percent of negative samples in individuals with symptoms, according to the FDA. The test also correctly identified 91 percent of positive samples and 96 percent of negative samples in asymptomatic persons.

However, because antigen tests are generally prone to both false negative and positive results, the FDA recommends that patients who not displaying COVID-19 symptoms treat positive results as "presumptively positive until confirmed by another test as soon as possible." This is likely to be particularly relevant for communities with fewer infections, because false positive results can be more common when antigen tests are used in populations where there's low prevalence of COVID-19.

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

New FDA Emergency Use Authorizations (EUAs) & Approvals

Manufacturer(s)	Product
Abbott	EUA for BinaxNow COVID-19 Ag Card rapid test
Quidel	EUA for Solana SARS CoV-2 rapid assay run on firm's Solana instrument
Quidel	EUA for QuickVue SARS Antigen test for COVID-19
MatMaCorp.	EUA for MatMaCorp COVID-19 2SF Test run on firm's Solas 8 portable nucleic acid analysis system
Acon Laboratories	EUA for ACON SARS-CoV-2 IgG/IgM Rapid Test
Hologic	EUA for Aptima SARS-CoV-2/Flu RT PCR assay
Quanterix	EUA for Simoa Semi-Quantitative SARS-CoV-2 IgG Antibody test
Hologic	Clearance for HIV-1 viral load monitoring Aptima HIV-1 Quant Dx assay, first dual-claim assay for diagnosis and viral load monitoring in U.S.
Genetworx	EUA for Genetworx Covid-19 Nasal Swab Test including self-collection kit materials

Manufacturer(s)	Product
PacificDx	EUA for COVID-19 Test including use with nasal swab specimens self-collected at home using RapidRona's self-collection kit
Ellume	COVID-19 Home Test, first EUA for emergency COVID-19 test that can be completed at home without a prescription
Horiba Medical	Clearance for Yumizen C1200 next-generation clinical chemistry system
Applied BioCode	EUA for SARS-CoV-2 Assay expanded to include use with pooled samples
Siemens Healthineers	510(k) clearance for Epoc NXS Host mobile computer
LabCorp	EUA for over-the-counter version of firm's Pixel by LabCorp COVID-19 Test Home Collection Kit
Mesa Biotech	510(k) clearance and CLIA waiver for Accula Strep A molecular test
Luminostics	EUA for Clip COVID Rapid Antigen Test
BioFire Defense	EUA for SARS-CoV-2 assay expanded to allow use with pooled samples
Quest	EUA for RC COVID-19 +Flu RT-PCR test for use with firm's Self-Collection Kit for COVID-19 +Flu
Quest	EUA for RC SARS-CoV-2 Assay, which is performed using Roche's authorized Cobas SARS-CoV-2 RT-PCR test, expanded to include use with pooled samples
Rheonix	EUA for SARS-CoV-2 assay expanded to include use on saliva samples
CDC	EUA for CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel expanded to include use with pooled samples
Innovita Biological Technology	EUA for Innovita 2019-nCoV Ab Test (Colloidal Gold) serology test
Cepheid	EUA for Xpert Xpress SARS-CoV-2 DoD test for use by DoD-designated CLIA labs
Cepheid	EUA for Xpert Omni SARS-CoV-2 RT PCR assay
Roche	EUA for Elecsys Anti-SARS-CoV-2 S electrochemiluminescence immunoassay run on firm's Cobas E analyzers

New CE Marks & Global Certifications

Notable European CE certifications announced during the period:

NEW CE MARKINGS IN EUROPE

Manufacturer(s)	Product(s)
Mologic	COVID-19 Rapid Antigen Test
Abbott	SARS-CoV-2 IgG II Quant antibody test run on firm's Architect and Alinity I systems

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FDA Watch, *from page 5*

Manufacturer(s)	Product(s)
Roche	Cobas PIK3CA Mutation test for identifying metastatic breast cancer patients who may benefit from phosphoinositide 3-kinase (PI3K) targeted therapy
Roche	Elecsys SARS-CoV-2 Antigen high-throughput test
Beroni	SARS-CoV-2 Antigen Test Kit (Colloidal Gold Method)
Bruker	FluoroType SARS-CoV-2/Flu/RSV winter respiratory virus panel
BioMérieux	SARS-COV-2 Respi R-Gene multi-analyte panel test
Anitoa Systems	Maverick portable qPCR instrument
Thermo Fisher Scientific	TaqPath COVID-19, Flu A/B, RSV Combo Kit
GeneFirst	COVID-19 Plus Detection Kit for detection of SARS-CoV-2, influenza A/B, and respiratory syncytial virus
EliTech Group	SARS-CoV-2 Plus Elite MGB Kit
Eurofins Technologies	GSD NovaGen SARS-CoV-2 rapid antigen test
Euroimmun	EuroRealTime SARS-CoV-2/Influenza A/B PCR test
C2N Diagnostics	PrecivityAD blood test for Alzheimer's
Paige	Paige Breast cancer detection software
LGC SeraCare	Anti-SARS-CoV-2 controls kit
Solvd Health	Genetic risk assessment test for opioid use disorder

Other international clearances announced during the period:

Manufacturer(s)	Country(ies)	Product(s)
Agilent Technologies	Japan	GenetiSure Dx Postnatal Assay
Horiba Medical	Canada	HealthCanada approval for Yumizen C1200 analyzer
Oxford Immunotec	South Korea	Ministry of Food and Drug Safety approval for T-Cell Select reagent kit
Illumina	China	National Medical Products Administration approval for NextSeq 550Dx instrument
Fluidigm	India	Central Drugs Standard Control Organisation approval for Advanta Dx SARS-CoV-2 RT-PCR Assay

2020 M&A Year in Review: Deal Making Was Low in Volume but High in Impact

Not surprisingly, the COVID-19 pandemic exerted a pronounced chilling effect on M&A activity in the diagnostic space as both buyers and sellers adopted a wait-and-see attitude. But the decline in deal volume belied the strategic significance of the deals that did come off in 2020. Here's a quick rundown of the year in M&A.

What Could Have Been

A strong case can be made that the biggest story in 2020 diagnostics M&A were the two blockbusters that didn't get consummated. The first was Thermo Fisher Scientific's proposed acquisition of Qiagen. It was all about timing. Confirming months of rumors, Thermo Fisher stepped forward with an $11.5 billion tender offer in March, representing a 23 percent premium over the molecular diagnostics' firm March 2 closing price. It seemed like a fair price. But then came the pandemic which boosted demands for Qiagen products in COVID-19 testing to unprecedented levels. Defying directors' recommendations, Qiagen shareholders threatened a revolt and forced Thermo Fisher to up the offer price. But it wasn't enough. In August, shareholders voted down the offer leaving Thermo Fisher to walk away with the $95 million in compensation provided for in the acquisition agreement in the event the deal got aborted.

The other potential game changer that didn't happen was Illumina's proposed $1.2 billion takeover of financially troubled Pacific Biosciences. The resistance of antitrust regulators, particularly in the U.K., created uncertainty and ultimately resulted in a mutual decision to call off the deal. However, PacBio did pocket a $95 million termination fee.

The Top 10 M&A Deals of 2020

There were six different billion-dollar M&A transactions in the diagnostics space in 2020, as compared to only five in 2019. Value-wise, the largest deal was the completion of the $21.4 billion of GE Biopharma by Danaher that was first announced in 2019. Perhaps the biggest surprise was the continued aggressiveness of Exact Sciences which followed up its $2.8 billion purchase of Genomic Health the year before with a pair of Top 10 acquisitions in 2020. Another surprise was Illumina's $8 billion reacquisition of its liquid biopsy spinoff, Grail, a decision criticized by many shareholders and financial analysts on the basis of both price and strategic fit.

Here's a rundown of the 10 biggest M&A deals that were closed or announced in 2020:

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2020 M&A Year in Review: Deal Making Was Low in Volume but High in Impact, *from page 7*

Top 10 Diagnostic M&A Deals of 2020 (By Deal Value)

Rank	Buyer	Target	Reported Price
1	Danaher	GE Biopharma	$21.4 billion cash + stock
2	Siemens Healthineers	Varian Medical Systems	$16.4 billion all cash
3	Illumina	Grail	$8.0 billion cash + stock
4	Blackstone	Ancestry.com	$4.7 billion
5	Exact Sciences	Thrive Earlier Detection	$2.15 billion cash + stock
6	Invitae	ArcherDX	$1.4 billion cash + stock
7	Sartorius	Danaher	$825 million
8	Exact Sciences	Base Genomics	$410 million
9	PerkinElmer	Horizon Discovery Group	$383 million cash*
10	Qiagen	NeuMoDx	$248 million cash

* Announced in 2020 with closing scheduled for 2021

M&A Report: CompuGroup Medical Makes Major LIS Play by Acquiring Schuyler House

It seems fitting that the pandemic year of 2020 should end not with a bang but a whimper. December was the slowest month in M&A deal making of not only this year but many years in recent memory with just a pair of transactions. However, the sluggish December and relative lack of deal volume in 2020 belies the strategic significance of the deals that did come down. See page 7 for a summary of the year's Top 10 diagnostics M&A deals.

A Lab Information Systems Game Changer

On Dec. 7, CompuGroup Medical (CGM) announced its acquisition of Valencia, California-based lab information systems (LIS) developer Schuyler House for an undisclosed price. By adding Schuyler House's modular reference labs and physician offices software products to its portfolio, the global eHealth solutions firm has now become the largest LIS provider in the U.S., according to a company statement.

"We are strengthening our product portfolio and our laboratory presence in the U.S.," noted **Benedikt Brueckle**, CGM's Senior Vice President U.S. & Canada. The addition of SchuyLab gives CGM greater flexibility and expertise to better serve labs performing clinical, toxicology, pain management, microbiology and molecular testing.

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

MERGERS, ACQUISITIONS & ASSET SALES

Acquiring Company	Target(s)	Deal Summary
CompuGroup Medical	Schuyler House	• Price: Undisclosed • Status: Closed • Acquisition of California-based lab information systems (LIS) firm makes CGM largest LIS company in U.S.
Impact Lab Group	HeartGenetic	• Price: Undisclosed • Status: No closing date announced • Acquisition of developer of bioinformatic software and personalized genetic tests which will continue to operate under its name in Portugal, Brazil, Netherlands, Spain and Italy

DX Deals: Siemens, California Health Network and Biopharm Research Company Partner for Enhanced Liver Fibrosis Testing

Although COVID-19 remains the driving force, non-pandemic-related strategic deal making continues. Among the most impactful deals announced in December is the partnership among Renown Institute for Health (IHI), Siemens Healthineers and Gilead Sciences to offer the Enhanced Liver Fibrosis (ELF) Test to individuals at risk for nonalcoholic steatohepatitis (NASH).

The ELF Test Project

Siemens' ELF Test, which is available in the U.S. via the Erlangen, Germany-based company's CLIA-certified Siemens Healthcare Laboratory, is a non-invasive blood test capable of quickly identifying patients who are at an elevated risk for developing cirrhosis and other liver-related clinical events. Unlike standard liver enzyme tests that detect liver damage after it has already occurred, the ELF Test make algorithm measurements of three serum-based biomarkers of active fibrosis to create a score assessing the risk for future disease progression and evaluation of whether a patient requires increased medical care and monitoring, according to IHI.

The plan is to offer the ELF Test to individuals at risk of NASH participating in a large genetic population health study called the Healthy Nevada Project. The expectation is that testing will be done on more than 30,000 participants over the next

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DX Deals: Siemens, California Health Network and Biopharm Research Company Partner for Enhanced Liver Fibrosis Testing, *from page 9*

two years. The partners didn't disclose the financial and other terms of the collaboration.

The new collaboration to make the ELF Test available for the Healthy Nevada Projects builds on an existing partnership between Renown IHI, an integrated health network serving Nevada and northeast California, and Gilead, a research-based biopharmaceutical company based in California, that began in July 2019. According to IHI, the organizations have been working together to collect and analyze de-identified genetic and electronic health data from 60,000 qualifying study participants to enhance the understanding of nonalcoholic fatty liver disease and NASH with the hopes of informing the development of treatment options for these diseases.

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

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS

Partner 1	Partner(s) 2+	Deal Summary
Illumina	Emedgene	• Objective: Develop software for diagnosing NGS-based rare diseases • Dynamic: Non-exclusive deal to integrate Emedgene's clinical rare disease application into Illumina's TruSight software suite
Illumina	Harvard Pilgrim Health Care	• Objective: Make whole-genome sequencing (WGS) available to certain Harvard Pilgrim pediatric patients • Dynamic: Risk-sharing agreement with Harvard Pilgrim to cover WGS via its lab providers network and both sides sharing genetic testing costs risk
Illumina	PierianDx	• Objective: Develop products for NGS-based cancer panel reporting • Dynamic: Expand existing partnership with PierianDx's genomic reporting products, including the Clinical Genomics Workspace and Clinical Genomics Knowledgebase, to be enabled for use with AmpliSeq for Illumina Focus panel, AmpliSeq for Illumina Myeloid panel, and Illumina TruSight Hereditary Cancer Panel

Partner 1	Partner(s) 2+	Deal Summary
Amoy Diagnostics	Merck KGaA	• Objective: Develop companion diagnostic test in China for Merck KGaA's novel MET inhibitor tepotinib (Tepmetko) • Dynamic: Amoy to develop and register AmoyDx Lung Cancer PCR Panel (11-in-1 Panel) for lung cancer and seek regulatory approval for use as a MET exon14 skipping companion diagnostic for tepotinib
Celsius Therapeutics	Servier	• Objective: Identify new drug targets for colorectal cancer • Dynamic: Celsius to use its single-cell genomics platform to analyze samples from colorectal cancer patients • Celsius gets undisclosed upfront payment and up to $700 million in milestone payments • Servier gets exclusive option to research, develop and commercialize products directed to up to three of the targets
Genosity	Gemini Therapeutics	• Objective: Develop molecular diagnostic for use in selecting patients for Gemini clinical trial of a dry age-related macular degeneration (AMD) drug candidate • Dynamic: Genosity to use samples from prospective study participants to create custom NGS panel to identify individuals with complement factor H (CFH) loss-of-function gene variants
Concert Genetics	Trapelo Health	• Objective: Provide comprehensive evidence-based molecular decision support for oncology • Dynamic: Integrate Trapelo Health's clinical decision support system linking providers, test labs and payors, with Concert's network of network of health plans and genomics labs
Bluejay Diagnostics	Toray Industries	• Objective: Develop point-of-care test to assess progression of COVID-19 • Dynamic: Toray to exclusively license its liquid biopsies technology to Bluejay who will perform clinical trials and seek regulatory approval outside Japan, including EUA from FDA

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DX Deals, *from page 11*

Partner 1	Partner(s) 2+	Deal Summary
Centogene	Alnylam Pharmaceuticals	• Objective: Perform clinical biomarker study of hereditary transthyretin-related amyloidosis (ATTRv) • Dynamic: TRAMmoniTTR study to longitudinally monitor status of symptomatic and asymptomatic participants with variants in TTR gene • Centogene to use its metabolomics profiling platform to discover and characterize novel biomarkers for ATTRv in TTR-positive participants
GeneMe	Biolyph	• Objective: Support scaling up of GeneMe's rapid isothermal molecular point-of-care COVID-19 assay • Dynamic: GeneMe to leverage Biolyph's lyophilization production, expertise, and capacity to expand lifecycle of its FRANKD test
TNG Dx	Premier Medical Laboratories	• Objective: Develop rapid RNA extraction protocol for use in SARS-CoV-2 diagnostics • Dynamic: Premier Medical to perform clinical and analytical validation studies on paired saliva samples collected by TNG Dx using anterior nasal sampling to develop extraction protocol, which will be submitted to FDA for EUA by year's end
Bio-Techne	Regulus Therapeutics	• Objective: Support development of Regulus' RGLS4326 autosomal dominant polycystic kidney disease (ADPKD) treatment • Dynamic: Bio-Techne to use its Simple Western instrument to develop biomarker assays to support assessment of levels of polycystin 1 (PC1) and polycystin 2 (PC2)
Canary Health Technologies	Divoc Laboratories	• Objective: Develop rapid, handheld breath test for detecting COVID-19 • Dynamic: Perform clinical trial on breath samples from 750 people who are either COVID-19 positive or don't have the virus with product launch in early 2021 if trial is successful

DISTRIBUTION, SALES & MARKETING AGREEMENTS

Product Owner	Distributor	Deal Summary
UgenTec	DMark Biosciences	• Products: UgenTec's FastFinder PCR analysis software products • Territory: Canada
NanoView Biosciences	Quantum Design	• Products: NanoView's ExoView platform • Territory: China • Exclusive
Cell Microsystems	Bucher Biotec	• Products: Cell's image-based single-cell CellRaft AIR System • Territory: Switzerland • Exclusive
HalioDx	Diagnosticos da America (DASA)	• Products: HalioDx's Immunoscore colon cancer risk-assessment test • Territory: Brazil • Exclusive
Sight Diagnostics	Phoenix Capital	• Products: Sight OLO blood analyzers • Territory: Middle East, starting with UAE and expanding to rest of Gulf Cooperation Council region
Cellex	Everlywell	• Products: Cellex's point-of-care SARS-CoV-2 antigen test • Territory: U.S.
Oxford Immunotec	Riken Genesis	• Products: T-Spot Discovery SARS-CoV-2 kit • Territory: Japan • Exclusive

LICENSES

Licensor	Licensee	Deal Summary
Arbor Biotechnologies	Lonza	Lonza gets right to use Arbor's CRISPR-based gene editing technology in its bioproduction products and services
Oncocyte	Burning Rock Biotech	Burning Rock gets exclusive right to use Oncocyte's DetermaRx test in China in exchange for upfront cash payments
Sherlock Biosciences	Tolo Biotech	Sherlock Biosciences licenses exclusive U.S. rights to CRISPR-Cas12 diagnostic technology; in return, Sherlock grants Tolo exclusive rights to CRISPR-Cas13 SHERLOCK diagnostic platform in Greater China

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DX Deals, *from page 13*

Licensor	Licensee	Deal Summary
Horizon Discovery	Sanyou Biopharmaceuticals	Horizon grants Sanyou two commercial licenses for its CHOSource platform for development of preclinical antibody drug projects and to support the clinical development and commercialization of its customers' human biotherapeutic products

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
Oncimmune	NHS Norfolk & Waveney Clinical Commissioning Group	Oncimmune to supply its EarlyCDT Lung blood test to the UK's NHS Norfolk & Waveney Clinical Commissioning Group

Emerging Tests: New Collaboration Seeks to Develop Handheld Breathalyzer Test for COVID-19, *from page 1*

received regulatory approval for testing people who are asymptomatic.

Focusing on the symptomatic is completely understandable. After all, people displaying symptoms of illness should be the priority when testing resources are in scarce supply. But what if there were a way to provide mass testing to asymptomatic people without diverting badly needed testing resources?

A New COVID-19 Testing Modality

Current COVID-19 diagnostics, including laboratory developed tests (LDTs), are based molecular, antibodies or antigen detection. So, a potential solution would be to develop a new modality using a different biomarker to detect the virus. One biomarker 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

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.

Announced on Nov. 30, the objective of the new collaboration is to develop and validate a hand-held digital breath test called ASU Detect CV19 which uses next-generation nanosensors and cloud-based artificial intelligence analysis to detect the SARS-CoV-2 virus in less than three minutes. The test is scalable, low cost and viable for use at the point of care for mass screening of both the symptomatic and asymptomatic.

Yeah, but will it work? To answer that question, the partners will perform a large clinical trial on 750 participants, some but not all of whom are positive for COVID-19. Participants will be asked to breathe into the ASU device for three minutes. The device will then translate their breath biomarkers into electronic signals which will be transmitted to a centralized "lab in the cloud" for analysis. Preliminary results were expected before the end of the year.

If the trial is successful, the plan calls for Canary to move quickly to apply for fast-track regulatory approval while continuing to trial the test in real-world settings such as airports, resorts and other high-density areas.

Other COVID-19 Diagnostic Products for Testing the Asymptomatic

Earlier this year, the FDA revised its templates to allow test makers whose products have already received EUA for testing symptomatic people to

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Emerging Tests: New Collaboration Seeks to Develop Handheld Breathalyzer Test for COVID-19, *from page 15*

apply for expansion of that EUA to cover use of the product for screening of asymptomatic individuals. Products that have received reissued EUA covering asymptomatic screening include:

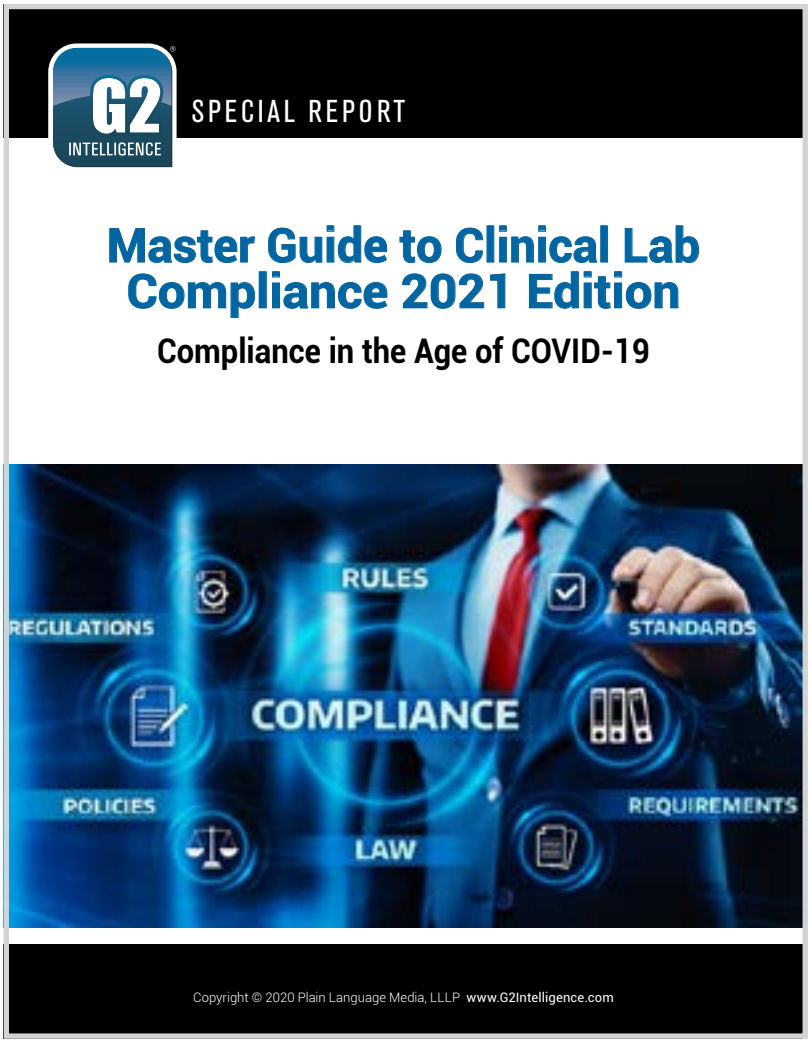
- LabCorp's COVID-19 RT-PCR test;
- LabCorp's Pixel by LabCorp COVID-19 Test Home Collection Kit;
- Hologic's Aptima SARS-CoV-2 assay;
- Hologic's Panther Fusion SARS-CoV-2 Assay;
- Helix OpCo's Helix COVID-19 Test;
- DxTerity Diagnostics' DxTerity SARS-CoV-2 RT-PCR CE Test;
- Centogene's CentoSure SARS-CoV-2 RT-PCR Assay;
- Gravity Diagnostics' Gravity Diagnostics SARS-CoV-2 RT-PCR Assay; and
- Kaiser Permanente Mid-Atlantic States' KPMAS COVID-19 Test.

Takeaway

While the new collaboration between Canary Health Technologies and Divoc Laboratories on handheld breathalyzer testing is hardly the first initiative to develop COVID-19 test products for the asymptomatic, what makes it unique is its modality. Rather than seeking to expand a molecular, antigen or antibodies test to cover screening of asymptomatic individuals, the partners are attempting to engineer a test specifically dedicated to this objective.

Master Guide to Clinical Lab Compliance 2021

Compliance in the Age of COVID-19



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