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Emerging Tests: The FDA's High-Stakes, High-Risk COVID-19 Serology Test Regulatory Strategy

Serology testing capable of distinguishing whether SARS-CoV-2 antibodies in a person's systems are due to a current or previous COVID-19 infection could play a pivotal role in the re-opening process and post-pandemic world. As with any new diagnostic tests, the FDA represents the gateway serological SARS-CoV-2 antibody tests must pass to reach the market. So, it's not surprising that the agency's policy—or, as some describe it, lack thereof—has become the focal point of attention now that the COVID-19 case curve has flattened out and society prepares to reemerge from lockdown.

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Diagnostic Deals: How Curative & KorvaLabs Created a Successful COVID-19 Testing Lab in Less than a Month

Say what you will about the current state and availability of COVID-19 diagnostic testing, the energetic, imaginative and speedy response by certain segments of the lab industry has been nothing short of heroic. A case in point is the collaboration between KorvaLabs and Curative to launch a COVID-19 testing firm in Southern California in record time.

Creating the Partnership

The story began in December 2019 when sepsis testing lab Shield Bio ran out of capital and had to close down. Shield CEO Fred Turner responded by founding Curative, Inc. The original plan was to focus on sepsis; but when the pandemic hit, it shifted gears and sought to create a COVID-19 testing lab. What it needed was an existing lab in the region that had

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Emerging Tests: The FDA's High-Stakes, High-Risk COVID-19 Serology Test Regulatory Strategy, *from page 1*

The FDA's Serology Testing Pathways

After initially resisting the idea, the agency has taken a test-now/regulate-later approach to COVID-19 diagnostic testing, permitting high-complexity CLIA and commercial labs to provide their own tests immediately upon validation without waiting from, and in some cases, even seeking Emergency Use Authorization (EUA) from the FDA. Among the four new pathways or "Policies," two can be used by test makers to launch SARS-CoV-2 antibody serology tests:

- Policy C, which allows for the launch of tests for use at the point of care upon validation without an EUA, provided that the test maker notifies the FDA immediately and submits an EUA application within 15 business days; and
- Policy D, an even less rigorous pathway which allows for launching of validated tests without having to secure EUA at all.

Manna from Heaven or Junk Science?

The positive aspect of the FDA policy is that new COVID-19 serology tests have become available in record time. The downside is that the tests are, to put it generously, unproven. Thus, among the 148 serology tests being provided, only seven have actually gotten EUA clearance, including assays from Dia Sorin, Chembio, Cellex and Abbott. The other 141 have passed through the Policy D pathway.

In addition to false claims by Policy D serology test makers about the capabilities of their products and suggesting that they have FDA approval, there's major concern about their lack of accuracy and reliability. Serology tests are especially vulnerable to specificity issues that can produce false positive results, leading people who are still susceptible to COVID-19 into falsely believing they're immune.

The FDA has come under fire for relying too heavily on serology testing and allowing "junk tests" to reach the market. Test makers are taking advantage of Policy D to market fraudulent tests, according to an April 24 House Oversight and Reform Subcommittee preliminary investigation report. Meanwhile, FDA efforts to encourage test makers to get clearance through Policy C and voluntarily submit their tests for independent validation are being ignored.

The congressional report cites the FDA for failing to "put forth standards and guidelines for serological antibody tests, departing from practices governing molecular tests." Compounding the problem, the agency has failed to take any enforcement action against any company for making false claims about its Policy D serology SARS-CoV-2 antibody test products.

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Takeaway

The FDA is doing everything it can to promote rapid development of serology testing that scientists and policy makers can rely on to evaluate the current scope of the COVID-19 pandemic and identify individuals who can safely return to work. But because of the low prevalence of COVID-19 among the general population, extremely high accuracy of test results is of critical importance. Regrettably, lack of specificity makes SARS-CoV-2 antibody testing prone to false positives, an accuracy flaw that carries potentially dangerous consequences. So, the current FDA policy of clearing such tests without the usual regulatory scrutiny is a roll of the dice with monstrously high stakes.

FDA Creates New Pathway for SARS-CoV-2 Serology Tests

On April 29, as we were going to press, the FDA announced that it has created a new "umbrella" pathway for EUA clearance of serology tests requiring test makers to submit tests for evaluation by an interagency testing group at the National Cancer Institute. Tests under review will be run against a panel of samples confirmed positive for anti-SARS CoV-2 IgM and IgG antibodies.

Tests will also be run against confirmed antibody negative samples or pre-COVID-19 samples, with 10 of these 80 negative samples being HIV positive. To receive clearance, tests reporting on both IgM and IgG must perform with overall sensitivity of 90 percent and specificity of 95 percent. Tests reporting the immunoglobulins separately must have sensitivity for IgM of at least 70 percent and 90 percent for IgG. Tests must also show no cross-reactivity with HIV.

FDA WATCH

Dozens of New COVID-19 Tests Get Emergency Clearance in April

As of April 30, 69 COVID-19 assays have received Emergency Use Authorization (EUA) from the FDA, including seven serology tests, one saliva-based test and an at-home testing kit. What began as a trickle in February and March became a stream in April, with 50 approvals for COVID-19 approvals. The chart below lists just the commercial test products that got the green light during the month.

Of course, there were also some significant new approvals for non-COVID-19 products. Here's a summary of key new FDA and CE European clearances in April 2020.

Continued on page 4

FDA WATCH, *from page 3*

New FDA Emergency Use Authorizations (EUAs) & Approvals

Manufacturer(s)	Product
Quidel	Expanded EUA for Lyra SARS-CoV-2 assay
BGI Americas (BGI Genomics US sub)	EUA for BGI Real-Time Fluorescent RT-PCR Kit
Luminex	EUA for NxTag CoV Extended Panel
Thermo Fisher Scientific	Clearance for ImmunoCAP Specific IgE Stinging Insect Allergen Components for identifying insect sting sensitivity
Roche	Clearance for Cobas HPV test for human papillomavirus for use with its high-throughput Cobas 6800/8800 systems
Qiagen	EUA for QiaStat-Dx Respiratory SARS-CoV-2 Panel, first "syndromic" testing product to be deployed in US
NeuMoDx	EUA for NeuMoDx SARS-CoV-2 Test Strip for use on NeuMoDx 288 Molecular + NeuMoDx 96 Molecular systems
Cellex	EUA for qSARS-CoV-2 IgG/IgM Rapid Test, first coronavirus serology test to get EUA clearance
Ipsum Diagnostics	EUA for COV-19 IDx, an RT-PCR-based SARS-CoV-2 test
Sectra	510(k) clearance for Sectra Digital Pathology Module for use in primary diagnostics
Becton Dickinson + BioGX	EUA for Sample-Ready hospital SARS-CoV-2 assay for use on BD Max system
Co-Diagnostics	EUA for Logix Smart Coronavirus COVID-19 Test
Luminex	EUA for Aries SARS-CoV-2 Assay
Gnomegen	EUA for COVID-19 RT-Digital PCR Detection kit for diagnosing SARS-CoV-2
Becton Dickinson	EUA for BD MAX ExK TNA-3 kit run on BD Max system
InBios International	EUA for Smart Detect SARS-CoV-2 rRT-PCR Kit
DiaCarta	EUA for QuantiVirus PCR diagnostic (Dx) test for COVID-19
Personal Genome Diagnostics	Clearance for its PGDx Elio Tissue Complete, NGS assay for genomic profiling of cancer
DNAe	Breakthrough Device designation for LiDia-SEQ platform and first assay
Atila Biosystems	EUA for iAMP COVID-19 Detection Kit
Specialty Diagnostic Laboratories	EUA for test for qualitative detection of a region in SARS-CoV-2 ORF1a/b gene
Orig3n	EUA for Novel Coronavirus Test for qualitative detection of two regions in SARS-CoV-2 nucleocapsid gene
Ortho Clinical Diagnostics	EUA for Vitros Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack and Calibrators serology test
Chembio Diagnostics	EUA for DPP COVID-19 serology point-of-care test and analyzer providing numerical readings for IgM and IgG antibody levels

Manufacturer(s)	Product
Qiagen	Clearance for use of Therascreen BRAF V600E RGQ PCR kit as companion diagnostic to BRAF inhibitor encorafenib (Pfizer/ Array BioPharma's Braftovi)
Incyte	Clearance for pemigatinib (Pemazyre) for previously treated, locally advanced or metastatic cholangiocarcinoma with FGFR2 fusions or rearrangements
GenoSensor	EUA for GS COVID-19 RT-PCR kit
Exact Sciences	EUA for SARS-CoV-2 RT-PCR test
Shanghai Fosun Pharmaceutical	EUA for COVID-19 RT-PCR test
Osang Healthcare	EUA for GeneFinder COVID-19 Plus RealAmp Kit
Trax Management Services	EUA for PCR-based SARS-CoV-2 test
Mobidiag	EUA for Novodiag PCR-based COVID-19 test
Seegene	EUA for PCR-based Allplex 2019-nCoV Assay
Abbott Laboratories	EUA for SARS-CoV-2 point-of-care test
Abbott Laboratories	EUA for SARS-CoV-2 IgG antibody serology test qualitatively detecting IgG antibodies
Abbott Laboratories	510(k) clearance for Blue i-Stat CG4+ cartridge for use with venous and arterial whole blood samples
Altona Diagnostics	EUA for RealStar SARS-CoV-2 RT-PCR Kit US
SD Biosensor	EUA for Standard M nCoV Real-Time Detection kit
Ortho Clinical Diagnostics	EUA for SARS-CoV-2 immunoassay
Autobio Diagnostics	EUA for Anti-SARS-CoV-2 Rapid Test immunoassay
DiaSorin	EUA for Liaison SARS-CoV-2 S1/S2 IgG serology assay detecting IgG antibodies in people who've been infected
Agilent Technologies	Clearance for PD-L1 IHC 22C3 pharmDx as companion diagnostic for Merck's pembrolizumab (Keytruda) on Dako Omnis platform

New CE Marks & Global Certifications

Notable European CE certifications announced during the period:

NEW CE MARKINGS IN EUROPE

Manufacturer(s)	Product(s)
Biocept	CE-IVD marking for Target Selector EGFR mutation detection assay
Erba Mannheim	CE marking for announced Monday ErbaLisa COVID-19 ELISA kits for detecting IgG and IgM antibodies
Vela Diagnostics	CE-IVD marking for ViroKey SARS-CoV-2 RT-PCR Test
JN Medsys	CE-IVD marking for ProTect COVID-19 RT-qPCR kit to detect N1, N2 and N3 regions of SARS-CoV-2

Continued on page 6

FDA WATCH, *from page 5*

Manufacturer(s)	Product(s)
Eurofins Technologies	CE-IVD marking for three different ELISA-based serology tests for SARS-CoV-2
Proteomics International Laboratories	CE marking for PromarkerD Immunoassay (IA) kit
PathoFinder	CE marking for RealAccurate Quadruplex Corona-plus PCR kit
Genetron Health	CE marking for Novel Coronavirus (SARS-CoV-2) RNA (PCR-Fluorescence Probing) Detection Kit
Beroni	CE marking for SARS-CoV-2 IgG/IgM Antibody Detection Kit
Genetic Signatures	CE marking for SARS-CoV-2 detection kit

Other international clearances announced during the period:

Manufacturer(s)	Country(ies)	Product(s)
Rendu Biotechnology	China	National Medical Products Administration emergency approval for SARS-CoV-2 nucleic acid detection kit

M&A Report: Danaher Closes $21.4 Billion GE Biopharma Acquisition

Although the COVID-19 pandemic has had a chilling effect on strategic acquisitions, M&A activity is still taking place, including the conclusion of the biggest deal in the diagnostics space in over a year.

The Danaher Blockbuster

First announced in February 2019, the $21.4 acquisition of General Electric's Biopharma business by Danaher closed at the end of March. Danaher financed the purchase with cash on hand, stock sales and issuances and funds raised through debts and credit facilities. The company also agreed to assume certain GE pension liabilities as part of the deal, which is so massive in size and geographical scope that it required antitrust and other approval in the US, Europe, Korea, Brazil, Russia, China, Israel and Japan.

The acquired Biopharma unit, comprised of single-use technologies, process chromatography hardware and related consumables, development instrumentation and consumables and cell culture media and service, will operate as a standalone company called Cytiva within Danaher's $6.5 billion Life Sciences segment. Other companies in the unit include Pall, Beckman Coulter Life Sciences, SCIEX, Leica Microsystems, Molecular Devices and Phenomenex. "GE Biopharma is renowned for providing best-in-class bioprocessing technologies and solutions," noted Danaher

CEO **Thomas P. Joyce, Jr.**, adding that it would provide "an excellent complement to our current biologics workflow solutions." The company previously indicated that it was expecting 45-50 cents per share earnings accretion for the first year of deal completion, but that was before the COVID-19 pandemic.

For its part, unloading GE Biopharma is part of GE's larger, ongoing restructuring plan to focus on its three core segments: aviation, power and renewable energy.

Thermo Fisher/Qiagen & Quest

Meanwhile, the other massive M&A deal in the diagnostics space, Thermo Fisher's proposed acquisition of Qiagen for $11.5 billion, remains on track. In recent corporate disclosures, Thermo Fisher indicated that it still expects the deal to close in the first half of 2021 and that it has raised $3.5 billion in US and European bond offerings to finance it.

One firm that has shelved M&A deals due to the pandemic is Quest Diagnostics. However, it's just a temporary reprieve. Quest Chairman and CEO **Steve Rusckowski** expressed "strong conviction" that negotiations will resume and that deals may be completed in the third quarter. He also indicated that M&A will continue to play a central role in the company's long-term business strategy and that the pandemic may actually accelerate acquisitions by aggravating the financial struggles of hospital and smaller regional labs and making them ripe for takeover.

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

MERGERS, ACQUISITIONS & ASSET SALES

Acquiring Company	Target(s)	Deal Summary
Danaher	General Electric biopharma business	• Price: $21.4 billion cash • Status: Closed • Danaher financing the deal with $3 billion from equity offering, cash on hand + proceeds of debt and/or new credit facilities issuance • GE business to operate as a standalone company called Cytiva within Danaher's $6.5 billion Life Sciences segment
Bio-Rad	Celsee	• Price: Undisclosed • Status: Closed • Bio-Rad acquires producer of Genesis system for isolating and analyzing single cells for cytometry, transcriptomics, multi-omics, rare-cell enrichment and enumeration and immune monitoring

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M&A Report, *from page 7*

Acquiring Company	Target(s)	Deal Summary
OpGen	Curetis GMbH	• Price: 2,662,564 new common shares of OpGen (73% stake) based on $24 million valuation of combined business with current OpGen holders keeping remaining 27% equity share • Status: Closed • Curetis to become wholly owned subsidiary of OpGen to create transatlantic, US-based, Nasdaq-listed company with a commercial-stage molecular diagnostics and bioinformatics franchise and pipeline focusing on infectious diseases and antimicrobial resistance
Genalyte	BaseHealth	• Price: Undisclosed • Status: Closed • Acquisition of data analytics firm results in combined company providing onsite, rapid diagnostics with data analytics capabilities
Haemonetics Corporation	Enicor	• Price: Undisclosed • Status: Closed • Maker of TEG Hemostasis Analyzer acquires German developer of EU marked ClotPro blood coagulation test system

Emerging Markets: The Money to Be Made on New SARS-CoV-2 $erology Test Products

SARS-CoV-2 serology antibody testing—reliably indicating whether persons with SARS-CoV-2 *have* COVID-19 or *had* COVID-19 and are thus presumably immune from getting it again—has the potential to provide the essential information scientists and policy makers need to re-open, monitor and secure the safety of the post-pandemic world. Such information can be used for:

- Measuring the extent of the pandemic among populations, including via results of mass screening to assess "herd immunity," i.e, whether a sufficient portion of the population is immune;
- Determining whether individuals can be safely allowed to return to work and society; and
- Developing COVID-19 vaccines and treatment, e.g., by identifying which people can donate blood for treatment of others.

The Serology Testing Goldmine

Naturally, test makers that can furnish reliable serology testing products stand to make boatloads of money. In fact, several already are. A new report from financial analysis firm Cowen offers a glimpse into the dollars to be made and being made in the short term, even at the current low reimbursement rates.

The Macroeconomic Perspective

50 million: That's the total number of COVID-19 tests of all types Cowen expects just the largest lab companies to produce per month by the end of June. Of these, 20 million would be serology tests. And that's just for clinical settings. Total tests would balloon if you add serology tests used for "broad employer screening."

$65 million: That's the rough US market size based on tests priced between $5 and $25 and utilization by the roughly 8.7 million people the US Bureau of Labor Statistics lists as being employed as healthcare practitioners, not counting repeat testing over time. When you account the population of more than 70 million students, this becomes a roughly $500 million market. And it's $1.2 billion when you consider employer screening and define the market as the total US workforce of nearly 160 million.

The Microeconomic Perspective

$300 million: That's what Abbott Laboratories is expecting to add to quarterly gross revenues, starting in June, via monthly distribution of 20 million of its SARS-CoV-2 IgG antibody tests, priced at roughly $5 apiece, qualitatively detecting IgG antibodies in human serum, which received EUA in mid-April. Of course, Abbott has also received FDA clearance for two other non-serological COVID-19 tests and has two others in the pipeline.

$1.2 billion: That's the quarterly gross revenue boost Roche is expecting, if and when it secures FDA clearance for its own serology test, at a reimbursement rate of $3 per test. EUA is expected to come in May.

Other companies that have secured EUA clearance for SARS-CoV-2 antibody serology assays include (in chronological order) Cellex, Chembio Diagnostics, Dia Sorin and Ortho Clinical Diagnostics. In addition to Roche, companies seeking and expected to quickly receive EUA for serology products in the pipeline include CE Mark and Siemens Healthineers.

Reimbursement of COVID-19 Testing: Private Payors

COVID-19 relief legislation, i.e., the *Families First Coronavirus Response Act* (FFCRA) and *Coronavirus Aid, Relief, and Economic Security Act* (CARES) require payors to cover COVID-19 testing without charging consumers for out-of-pocket expenses. On April 11, CMS issued guidance for implementing these requirements.

The COVID-19 Lab Test Reimbursement Rules

Enacted on March 18, FFCRA requires 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 or diagnosing COVID-19 (which, for simplicity's sake, we'll refer to collectively as "COVID-19"). To ensure testing is free, FFCRA bans imposition of: i. cost-sharing requirements like deductibles, copayments and coinsurance; and ii. prior authorization and other medical utilizaton requirements.

On March 27, CARES amended FFCRA to include a broader range of diagnostic items and services that plans and issuers must cover without cost-sharing or prior authorization requirements. CARES Act also requires plans and issuers to reimburse providers of COVID-19 diagnostic testing an amount equal to its negotiated rate with the provider; if there is no negotiated rate, reimbursement must be at the cash price for such service listed by the provider on a public website. The plan or issuer may also negotiate—but not unilaterally apply—a rate with the provider that's lower than the listed cash price.

3 Key Takeaways from the CMS Guidance

There are three key points in the guidance that lab managers need to know to ensure they receive proper reimbursement for COVID-19 tests during the emergency:

1. The Source of the Test Order

The guidance clarifies that the no-cost-sharing-requirement applies to COVID-19 tests ordered as a result of urgent care visits, emergency room visits and in-person and telehealth visits to a doctor's office.

2. The COVID-19 Tests Covered

According to the guidance, covered COVID-19 tests include:

- All FDA-authorized coronavirus tests, which includes serology tests receiving emergency use authorization (EUA);
- Tests that developers for which test makers have requested but not yet received EUA; and
- Diagnostic tests developed in and authorized by states.

3. The Effective Date

The COVID-19 testing reimbursement requirements apply to all testing and related services furnished on or after March 18, 2020 and will continue to apply for as long as the emergency lasts. is retroactive for testing and related services provided on or after March 18.

Reimbursement of COVID-19 Testing: Medicare

How about some good news for a change? On April 15, CMS announced that it was increasing reimbursements for high-throughput SARS-CoV-2 lab tests. Here are the three key takeaways.

1. Which Tests Qualify for the Increase

The reimbursement bump applies to tests using high-throughput technologies allowing for increased capacity and faster results. High-throughput tests, CMS explains, can process at least 200 specimens per day using "highly sophisticated equipment that requires specially trained technicians and more time-intensive processes to assure quality." The agency lists examples of high-throughput technology, including:

- Roche's Cobas 6800 and 8800 systems;
- Abbott's m2000 system;
- Hologic's Panther Fusion system;
- Cepheid's GeneXpert's Infinity system; and
- NeuMoDx's 288 Molecular system.

2. The New Reimbursement Rates

Starting with tests performed on April 14, CMS will pay $100 for eligible SARS-CoV-2 high-throughput tests. That's a significant increase from the original rate set in March as $35.91 or $35.92 for labs using the test developed by the US Centers for Disease Control and Prevention, and between $51.31 and $51.33 for non-CDC tests. Reimbursement for tests that don't use high-throughput technology will remain subject to Medicare Administrative Contractors discretion, with the current going rate of about $51 per test.

3. Which Billing Code to Use

Labs can bill for COVID-19 tests using:

- **Code U0003** for PCR-based coronavirus tests; and
- **Code U0004** for tests using any technique with high-throughput technology.

Diagnostic Deals: How Curative & KorvaLabs Created a Successful COVID-19 Testing Lab in Less than a Month, *from page 1*

the testing equipment, facility and capability to quickly adapt to COVID-19 testing.

KorvaLabs fit the bill. The San Dimas-based high-throughput lab specializing in sports drug testing was willing to partner. KorvaLabs would supply the infrastructure and Curative the infectious disease testing expertise.

Developing the Assay

The next thing the partners needed was a laboratory developed SARS-CoV-2 test. Within 10 days, that assay was created. The team brought the test to KorvaLabs, validated it and began performing it five days later. And on April 17, the Curative-Korva SARS-CoV2 assay received Emergency Use Authorization (EUA) from the FDA.

What distinguishes the Curative-Korva assay from other COVID-19 tests is its capacity to detect SARS-CoV-2 nucleic acids in not only oropharyngeal, nasopharyngeal and nasal swabs, but also oral fluid specimens, an extremely valuable trait given the shortages of nasal swabs. Of equal advantage was that samples can be self-collected with almost any type of sterile swab and without need of any special collection device. Using Zymo Research's DNA/RNA Shield to stabilize the sample RNA, specimens are transported, stored at room temperature and tested within 24 hours of collection.

Launching the COVID-19 Testing Lab

Because the lab was set up exclusively for COVID-testing, the team was able to arrange workflows to avoid other bottlenecks, e.g., use of a Norgen Biotek kit allowing for either manual or robotic extraction. Doing just COVID-19 testing also enabled the lab to be flexible in finding reagents, extraction kits and swabs.

The lab is now doing up to 5,000 tests per day, including first responders, and hasn't yet reached its testing capacity. Meanwhile, Los Angeles City and County drive-through test sites are also using the Curative-KorvaLab test service.

Takeaway

Four weeks. That's all it took for Curative and KorvaLabs to partner, develop an assay, secure FDA approval and open a COVID-19 testing lab providing 5,000 tests per day. It's a remarkable story and, let's hope, an inspiration and model for many others around the country.

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Here's a summary of the key strategic diagnostic deals announced in April 2020:

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS

Partner 1	Partner(s) 2+	Deal Summary
Merck	Institute for Systems Biology	• Objective: Develop COVID-19 vaccines and treatments • Dynamic: Research collaboration to discover and define to uncover and define molecular mechanisms of SARS-CoV-2 infection and COVID-19 development
Qiagen	Gilson	• Objective: Enable researchers to limit operator-independent variation in manual nucleic acid extraction results and improve workflow traceability • Dynamic: Research collaboration integrating integrate Gilson's Trackman Connected digital bench tools + Qiagen's manual nucleic acid extraction kits
Leinco Technologies	Vanderbilt University Medical Center	• Objective: Develop immunodiagnostic test to detectSARS-CoV-2 • Dynamic: Leinco to scale up production of its most promising antibodies to co-develop a test with antibody sequences discovered in Vanderbilt Vaccine Center
CareDx	Johns Hopkins University	• Objective: Launch of Allosure Lung Allograft Remote Monitoring (ALARM) to measure impact of AlloSure and RemoTraC on lung transplant patients • Dynamic: CareDx's RemoTraC is a remote home-based blood draw product using mobile phlebotomy for AlloSure and AlloMap surveillance tests
Mission Bio	Agilent Technologies	• Objective: Comarket Mission Bio's Tapestri single-cell analysis platform with unspecified Agilent products • Dynamic: Deal targets North America and follows 2019 deal between partners to market Tapestri in China

Continued on page 14

Diagnostic Deals, *from page 13*

Partner 1	Partner(s) 2+	Deal Summary
ArcherDX	Premier Applied Sciences	• Objective: Provide personalized genomic testing • Dynamic: Premier to identify eight of its member institutions to implement ArcherDX Stratafide test, in a research-use-only capacity as part of retrospective study to evaluate its sequencing performance compared to other tests
Indivumed	Personalis	• Objective: Develop personalized oncology products • Dynamic: Integrate Indivumed's IndivuType multiomic cancer database with genome and transcriptome-level data collected for Personalis' advanced cancer genomics technology
Curetis (subsidiary of Opgen)	Karolinska Institute	• Objective: Identify bacterial co-infections in patients with COVID-19 pneumonia • Dynamic: Utilize Curetis' Unyvero system and Hospitalized Pneumonia panel
True Diagnostics	Veravas + Infectolab Americas	• Objective: Develop and commercialize rapid, point-of-care SARS-CoV-2 immunoassay • Dynamic: VeraTest SARS-CoV-2 IgA/IgG Rapid Test for detecting immunoglobulin A and G antibodies against SARS-CoV-2 in blood within 15 minutes to combine True Diagnostics' TrueDx lateral flow immunoassay technology with Veravas' VeraPrep clean and VeraPrep capture technologies
Nimble Therapeutics	Svar Life Science	• Objective: Develop tests for autoimmune diseases using biomarkers discovered using Nimble's human proteome immunoprofiling technology starting with rheumatoid arthritis • Dynamic: Nimble to receive undisclosed upfront payment as well as milestone payments and royalties on product sales
ProMis Neurosciences	University of British Columbia (UBC)	• Objective: Develop test to assess immunity to SARS-CoV-2 • Dynamic: UBC to lead research team seeking to create high-throughput serological assay that can detect presence of SARS-CoV-2 antibodies for identifying who has virus immunity and who remains at risk for infection
Bosch Healthcare Solutions	Randox Laboratories	• Objective: Develop fully-automated coronavirus test for Bosch's point-of-care Vivalytic system • Dynamic: Expansion of current molecular diagnostic partnership with new test to be part of a viral respiratory tract infection (VRI) panel testing for nine other viruses, including influenza A and B and all known coronaviruses, with turnaround time of 2.5 hours

Partner 1	Partner(s) 2+	Deal Summary
Novacyt	BioType Diagnostic	• Objective: Manufacture Novacyt's COVID-19 test kits • Dynamic: Dresden, Germany-based BioType has already delivered first batches of for final assembly to Primerdesign, Novacyt's UK-based molecular diagnostics division
Oxgene	Native Antigen Company	• Objective: Increase antigen manufacturing capabilities reagents for development of SARS-CoV-2 diagnostics and vaccines • Dynamic: Leverage Oxgene's Adenoviral Protein Machine technology to deliver high-purity recombinant proteins
Amgen	Adaptive Biotechnologies	• Objective: Develop human antibody-based treatments for COVID-19 • Dynamic: Mutually exclusive partnership combining Adaptive's immune repertoire sequencing technology with Amgen's expertise in antibody therapy development to discover and develop fully human neutralizing antibodies targeting SARS-CoV-2
Zymo Research	Tecan	• Objective: Launch ready-to-go product to streamline viral DNA/RNA extraction from nasopharyngeal swasbs, oropharyngeal swabs, saliva, sputum, plasma and serum • Dynamic: Use Tecan's DreamPrep NAP workstation, featuring Zymo's Quick-DNA/RNA Viral MagBead Kit, to simplify the process by offering pre-loaded scripts that are being validated for COVID-19 assays by high complexity testing labs
Sophia Genetics	Paragon Genomics	• Objective: Launch new product combining Sophia's analytics services to Paragon's recently launched CleanPlex SARS-CoV-2 panel for COVID-19 detection • Dynamic: Expand existing partnership by combining Paragon's new panel reagent kit for whole-genome sequencing of novel coronavirus with Sophia's cloud-based platform

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Diagnostic Deals, *from page 15*

DISTRIBUTION, SALES & MARKETING AGREEMENTS

Product Owner	Distributor	Deal Summary
Becton Dickinson + BioMedomics	Henry Schein	• Products: BD/BioMedomics' commercial point-of-care SARS-CoV-2 test • Territory: US • Exclusive
Biolidics	Aytu BioScience	• Products: At least 1.25 million of Biolidics' serology COVID-19 IgG/IgM Rapid Tests • Territory: US • Exclusive
Oncocyte	CORE Diagnostics	• Products: Oncocyte's DetermaRx test • Territory: India, Middle East, Africa
Acumen Research Laboratories	United Global Alliance	• Products: Acumen's Acu-Corona 2.0 test kit • Territory: Africa and international healthcare organizations
Predictive Laboratories (subsidiary of Predictive Technology)	Wellgistics	• Products: Predictive's point-of-care Assurance AB COVID-19 IgM/IgG Rapid Antibody Test • Territory: US • Exclusive
Credo Diagnostics Biomedical	A. Menarini Diagnostics	• Products: Credo's SARS-CoV-2 kit and other assays for respiratory syncytial virus and Group Strep A diagnosis • Territory: Undisclosed • Exclusive

LICENSES

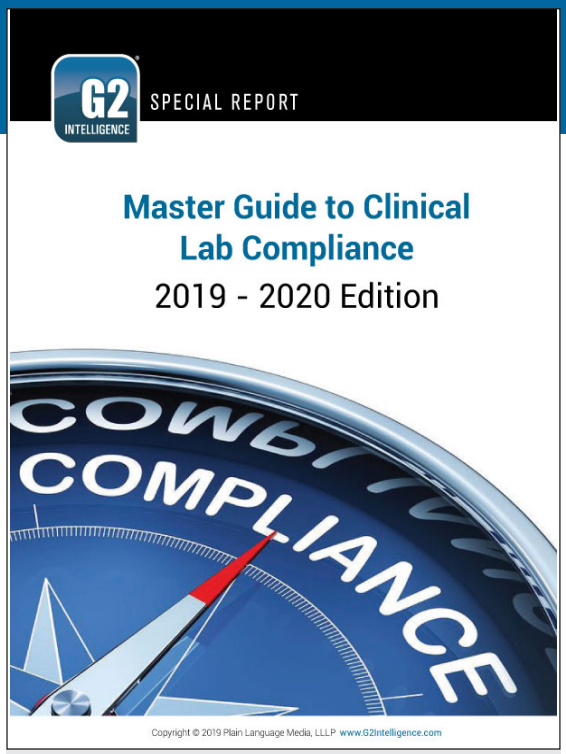
Licensor	Licensee	Deal Summary
Yale University	Elysium Health	Elysium acquires exclusive rights to Yale's DNA methylation biomarkers of aging and cellular senescence
Yale University	Veracyte	Veracyte acquires exclusive rights to Yale's genomic test for predicting disease progression in patients with idiopathic pulmonary fibrosis (IPF) for use on the nCounter Flex Analysis System, which Veracyte exclusively licensed from NanoString
Mount Sinai's Icahn School of Medicine	Biomerica	Two separate licensing agreements for for technologies related to a lab-based serological test for SARS-CoV-2
ERS Genomics	Axxam	Axxam gains access to ERS' CRISPR-Cas9 patent portfolio to support its integrated discovery service platform

SUPPLY, SERVICE & TESTING AGREEMENTS

Supplier/Servicer	Client/User	Deal Summary
Health Service Executive	Genomics Medicine Ireland + National Virus Reference Laboratory	HSE to supply reagents enabling GMI and NVRL to ramp up SARS-CoV-2 testing
Twist Bioscience	Vanderbilt University Medical Center	Twist to supply VUMC with antibodies and synthetic DNA to support development of potential COVID-19 therapies

Protect Your Lab against Growing Legal Risk!

Master Guide to Clinical Lab Compliance 2019-2020 Edition



Lab Compliance Essentials **covers:**

- Latest Fraud and Abuse Laws
- Rules and Regulations
- False Claims Act
- Anti-Kickback Laws
- Stark Laws
- "*Qui tam*" provisions
- Anti-retaliation provisions
- FCA enforcement actions
- Billing Practices
- 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**