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Industry Buzz: Market for LDTs Expected to Top $17 Billion by 2025

Even as the battle over FDA regulatory control over laboratory developed tests (LDTs) intensifies, the economic stakes get bigger. The current market value for LDTs is $12 billion. But a new report from a leading diagnostics industry analyst estimates that figure to grow to nearly $17.7 billion by 2025.

LDTs and the Pandemic

The LDT market was growing even before the pandemic, albeit at a more modest rate, thanks to the development polymerase chain reaction (PCR), next generation sequencing (NGS) and microarrays technologies enabling labs to meet

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Diagnostics Deals: JetBlue Partners with Vault Health to Offer Travelers At-Home COVID-19 Testing

COVID-19 has greatly complicated air travel from country to country and even state to state. While entrance rules vary from place to place, a number of jurisdictions are allowing travelers to avoid quarantine and self-isolation if they can prove they tested negative for the virus. As a result, some airlines have teamed with lab companies to offer customers with travel plans the chance to be tested before their flights. And now one airline has taken the model to the next level by providing, at-home saliva-based testing.

The JetBlue Collaboration with Vault Health

On Sept. 30, JetBlue announced that it has teamed with Vault Health, a men's healthcare technology platform offering

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Industry Buzz: Market for LDTs Expected to Top $17 Billion by 2025, *from page 1*

the need for new and improved tests for cancer, genetic disorders and infectious diseases. However, according to the new report published by Kalorama Information, the unprecedented demand for new COVID-19 diagnostic tests has "changed the landscape of LDTs."

Many of the first COVID-19 tests to receive Emergency Use Authorization (EUA) were LDTs. These included innovative tests covering the gamut from RT-PCR molecular to serologically-based antibody and antigen assays. Development of COVID-19 LDTs is expected to continue despite the FDA's recent announcement that it will no longer provide EUA review of such tests.

Most of the LDTs on the market today are small-volume tests, Kalorama notes. But there are also a handful of large-volume LDTs based on NGS and other technologies that can't be easily packaged into kits or shipped to the labs that perform the test. Oncology remains the largest segment of the LDT market.

The Kalorama Report

Kalorama's market growth projections are based on data on all clinical tests developed by labs for their own use, as opposed to IVD kids manufactured and sold by diagnostic companies for use by many different labs. The capital for growth exists. According to Kalorama, the development of new LDTs and growing revenues generated by current products have attracted investors and companies seeking targets for acquisition.

However, there are also concerns that have the potential to limit growth, including the reluctance of payors to cover LDTs, particularly those carrying high costs. Kalorama suggests that this may eventually lead labs and companies entering the market via diversification or acquisition to offer LDTs as kits. But Kalorama also expects this transition to be slow due to the current favorable regulatory environment.

The Prospects for Growth of Coronavirus LDTs

In addition, the recent FDA abdication of EUA review may slow the development of LDTs for COVID-19 by creating new reimbursement uncertainties. *The Family First Coronavirus Response Act* (FFCRA) requires commercial payors to cover medically necessary SARS-CoV-2 testing without cost sharing, but only if they have EUA from the FDA. Consequently, labs developing new SARS-CoV-2 LDTs face the prospect of not being reimbursed for their tests.

In addition to reimbursement risk, eliminating EUA review of LDTs for coronavirus heightens test makers' liability exposure by stripping away the immunity protections afforded by the *Public Readiness and Emergency*

LIR

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Preparedness Act (PREP). Like reimbursement under FFCRA, immunity from claims for use of tests during the public health emergency under PREP applies only to tests with EUA. And because of the urgency of the situation and need to get tests out faster than normal, test makers need these liability protections in case things go wrong. COVID-19 litigation has already become big business for trial lawyers and labs that develop inaccurate or faulty LDTs will be easy targets.

While it's not full FDA approval, EUA status also raises the credibility of a lab test product in the eyes of payors, clinicians and even patients. So, taking EUA off the table may make it harder for new LDTs to compete in the market, particularly against tests that have EUA.

Inside the Lab Industry: Equity Fund Acquires Controlling Stake in Ancestry.com as Demand for At-Home Genetic Testing Fades

Many believe that the boom for direct to consumer genetic testing had passed even before the pandemic began. Still, the sector is abuzz with strategic activity. In August, private equity firm Blackstone acquired a controlling interest in Ancestry.com for $4.7 billion. With sales in decline, the deal raises ominous questions and privacy concerns about Blackstone's intentions with regard to Ancestry.com users' data.

Background

Ancestry.com is a leader in digital family history services, with operations in more than 30 countries, more than three million paying subscribers across its Ancestry.com online properties and over $1 billion in annual revenue. Ancestry.com started in 1996 as a website for users to trace their genealogy. Nearly a decade later, the company expanded into DNA testing.

Direct-to-consumer genetic genealogy testing reached its zenith in 2018, propelling total sales from Ancestry, 23andMe, and other DTC gene testing companies to roughly $26 million. But sales of at-home testing kits have slumped since then as the market becomes more saturated. Both Ancestry and rival consumer testing giant 23andMe announced layoffs this year.

Ancestry tried to kickstart sales this August by announcing the launch of AncestryHealth, a $179 DNA testing kit that uses next generation sequencing to provide adult consumers information on their inherited health risks. That was the same month that Blackstone bought up the majority of Ancestry stock shares.

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Inside the Lab Industry: Equity Fund Acquires Controlling Stake in Ancestry.com as Demand for At-Home Genetic Testing Fades, *from page 3*

Privacy Concerns

So, why would Blackstone be willing to shell out close to $5 billion for Ancestry at a time when the future prospects for DTC genetic testing seem so dim—or at least not nearly as bright as they did two years earlier? Experts suggest the massive equity fund had something else in mind, specifically Ancestry's enormous database of millions genetic date-information on millions of people. And those implications are not lost on advocates of personal privacy.

Some have questioned why Blackstone, the world's largest real estate owner, with ownership stakes in Change Healthcare would want with personal genetic information of Ancestry customers. They note the difference between the Blackstone investment and GlaxoSmithKline's $300 million investment in 23andMe in 2018, which bore fruit when GlaxoSmithKline started human trials of a cancer drug that resulted from the partnership with 23andMe.

Ancestry's current privacy policy allows it to market new products from the company or its business partners, but then goes on to say it will not share users' genetic information with insurers, employers, or third-party marketers without their express intent. Privacy advocates, however, say that is not enough and additional consumer protections are needed.

FDA WATCH

Agency Temporarily Allows Modifications of Influenza and RSV Tests Without Premarket Notification

On Oct. 13, the FDA issued new guidance on molecular diagnostic tests for influenza and respiratory syncytial virus (RSV). The upshot of the guidance is to temporarily allow makers of flu and RSV tests that the agency has already cleared to make certain modifications to those products without submitting 510(k) premarket notification in the interest of making the tests more widely available while also not using up reagents needed for SARS-CoV-2 testing.

Background

There's significant overlap in warning signs and symptoms between SARS-CoV-2 and other

respiratory viral infections, including influenza and RSV, the guidance explains. "Increased availability of molecular influenza tests during the COVID-19 pandemic is important due to the similarity in symptoms

between COVID-19 and the seasonal influenza." The guidance also notes that because of this overlap in symptoms, molecular influenza tests are often offered as part of a panel of tests including RSV.

Diagnostic tests for SARS-CoV-2 and other respiratory viral infections generally use many of the same components. For example, the same specimen collection devices and transport media required to perform many FDA-cleared molecular influenza tests are also needed for most molecular diagnostic SARS-CoV-2 assays. And, of course, those devices and media are currently in short supply.

Accordingly, the guidance states that for the duration of the COVID-19 public health emergency, the agency "does not intend to object" to the addition of certain transport media types and sample types for previously FDA-cleared molecular flu and RSV tests. Such modifications won't require submission of a 510(k) premarket notification so long as they don't "create undue risk in the light of the public health emergency." The policy doesn't apply to tests and devices for other viruses, antigen-based tests, multiplex respiratory panels, or multiplex molecular tests that include SARS-CoV-2 targets, the guidance specifies.

Modifications Not Requiring Premarket Notification

Specifically, tests previously indicated for use with samples collected in viral transport media may now be modified to use samples collected in sterile phosphate buffered saline, "including molecular grade PBS and other similar formulations such as Dulbecco's PBS," as well as into sterile normal saline. Also on the agency's "does-not-intend-to-object" list are modifications to add healthcare provider-collected anterior nares or mid-turbinate specimens, provided that the test is already cleared for use with nasopharyngeal swab samples.

Modifications Still Requiring Premarket Notification

The guidance also cites specific modifications that the agency believes *would* create undue risk and thus wouldn't be subject to the temporary relaxation of premarket notification requirements, including:

- Adding a sample type not identified in the examples cited as not creating undue risk to an FDA-cleared molecular influenza and RSV test;
- Adding an indication for use with self-collected specimens to an FDA-cleared molecular influenza and RSV test;
- Adding a transport media not identified in the not-creating-undue risk examples to an FDA-cleared molecular influenza and RSV test; or
- Adding an over-the-counter (OTC) use or new patient population (e.g., pediatrics) to the indication for an FDA-cleared molecular influenza and RSV test.

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The guidance also instructs developers to provide labeling information to help users understand whatever modifications have been made and to verify and validate performance of the modified test.

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Here are some of the key FDA EUAs and approvals announced in October:

New FDA Emergency Use Authorizations (EUAs) & Approvals

Manufacturer(s)	Product
Celltrion	EUA for Sampinute COVID-19 Antigen MIA magnetic force-assisted electrochemical sandwich immunoassay
Foundation Medicine	Clearance for FoundationOne Liquid CDx test as companion diagnostic for three new targeted cancer therapies, including alpelisib (Novartis' Piqray) in advanced or metastatic breast cancer, rucaparib (Clovis Oncology's Rubraca) in advanced ovarian cancer, and alectinib (Genentech's Alecensa) in metastatic non-small cell lung cancer
Foundation Medicine	Clearance for FoundationOne CDx test as companion diagnostic for use with larotrectinib (Bayer's Vitrakvi) to identify cancer patients with neurotrophic receptor tyrosine kinase fusions
Scopio Labs	510(k) clearance for X100 hematology imaging and analysis system and Full Field Peripheral Blood Smear application
Abbott Laboratories	EUA for SARS-CoV-2 IgM antibody test
Thermo Fisher Scientific	EUA for OmniPath COVID-19 Total Antibody ELISA Test
DNA Genotek	EUA for OMNIgene·ORAL OM-505 and OME-505 saliva collection devices
Clinical Enterprise	EUA for EmpowerDX At-Home COVID-19 PCR Test Kit
LumiraDx	EUA for SARS-CoV-2 RNA STAR Complete assay
MiR Scientific	Breakthrough Device Designation for MiR Sentinel PCC4 Assay for prostate cancer
Spectrum Solutions	EUA for SDNA-1000 Saliva Collection Device
Access Bio	EUA for CareStart COVID-19 Antigen test
Genalyte	EUA for Maverick SARS-CoV-2 Multi-Antigen Serology Panel v2
Beckman Coulter	EUA for Access SARS-CoV-2 Immunoglobulin M (IgM) assay
Beckman Coulter	EUA for Access Interleukin-6 (IL-6) immunoassay
Seasun Biomaterials	EUA for AQ-TOP COVID-19 Rapid Detection Kit Plus
Zeus Scientific	EUA for ELISA SARS-CoV-2 IgG Test System
UCLA	EUA for SwabSeq COVID-19 Diagnostic Platform
BioFire Diagnostics	EUA for BioFire Respiratory Panel 2.1-EZ
Quidel	EUA for Sofia 2 Flu + SARS Antigen FIA

Manufacturer(s)	Product
Becton Dickinson	510(k) clearance for BD FACSLyric Flow Cytometer with integrated BD FACSDuet Sample Preparation System
LabCorp	EUA for RNA extraction method for SARS-CoV-2 testing
Genetron	Breakthrough Device Designation for HCCscreen, blood-based NGS test for early detection of liver cancers
Chembio Diagnostics	Premarket approval for DPP HIV-Syphilis System
DiaSorin	EUA for Liaison SARS-CoV-2 IgM Assay
DiaSorin	Approval for six hepatitis B serology assays
Tempus	EUA for iC SARS-CoV-2 test
Alimetrix	EUA for SARS-CoV-2 RT-PCR Assay
NanoEntek America	EUA for Frend COVID-19 total Ab test
Nirmidas Biotech	EUA for Nirmidas COVID-19 (SARS-CoV-2) IgM/IgG Antibody Detection Kit
Centogene	EUA for CentoSure-SARS-CoV-2 RT-PCR Assay

New CE Marks & Global Certifications

Notable European CE certifications announced during the period:

NEW CE MARKINGS IN EUROPE

Manufacturer(s)	Product(s)
Ortho Clinical Diagnostics	Vitros SARS-CoV-2 Antigen test
DiaSorin	Liaison SARS-CoV-2 Ag chemiluminescence immunoassay
PerkinElmer	PKamp Respiratory SARS-CoV-2 RT-PCR Panel for detecting and differentiating SARS-CoV-2, influenza A/B viruses, and RSV
Kantaro Biosciences	COVID-SeroKlir and COVID-SeroIndex quantitative SARS-CoV-2 IgG antibody test kits
Becton Dickinson and CerTest Biotec	Viasure SARS-CoV-2 (N1 + N2) Real Time PCR Detection Kit run on BD Max system
Becton Dickinson	Clearance for BD Multitest 6-Color TBNK Reagent with BD Trucount Tubes expanded to cover use to identify and enumerate T-cell subtypes in COVID-19 patients
Specific Diagnostics	Reveal, a rapid antimicrobial susceptibility testing system
Siemens Healthineers	Clinitest Rapid COVID-19 Antigen Test
Thermo Fisher Scientific	EliA SARS-CoV-2-Sp1 IgG test and OmniPath COVID-19 Total Antibody ELISA Test
Oxford Nanopore Technologies	LamPore SARS-CoV-2 sequencing test
Omixon	AzureSeq-200 RT-PCR kit, an extraction-free viral RNA detection kit to detect SARS-CoV-2

Other international clearances announced during the period:

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Manufacturer(s)	Country(ies)	Product(s)
Yourgene Health	Australia	Therapeutics Goods Association approval of Iona Nx NIPT workflow as a Class 3 medical device

Reimbursement: CMS Disguises COVID-19 Rate Cut as Incentive to Process Tests Faster

Few would argue that the current turnaround time for COVID-19 testing is too long. But there are good reasons why it's taking labs so long to process and report test results, including unprecedented volume in demand and shortages in supplies and personnel. So, the idea of offering labs add-on payments as an incentive to speed up the process is one based on ignorance. And when you add in the fact that the add-on payment is actually just a recovery of a rate cut, it becomes almost cynical. Regrettably, both of these things are true of the new Medicare reimbursement policy for COVID-19 testing in 2021 announced by CMS on Oct. 15.

Medicare Reimbursement of COVID-19 Testing

When the public health emergency first began, Medicare paid labs $51 per test for high throughput COVID-19 diagnostic tests. Recognizing that the rate was inadequate, CMS raised it to $100 per test. However, effective Jan. 1, 2021, labs will only qualify for the $100 payment rate if they complete the test within two calendar days of collecting the specimen. Labs that take longer than two days will be paid only $75 per test.

The Way It Works

Technically, the amended Administrative Ruling (CMS 2020-1-R2) lowers the base rate payment amount for COVID-19 diagnostic tests run on high throughput technology to $75. However, labs will qualify for a $25 add-on payment if:

- They complete the billed test in two calendar days or less; AND
- They complete the majority of high throughput COVID-19 tests in two calendar days or less for **all** of their patients (not just their Medicare patients) in the previous month.

Labs that qualify will use HCPCS code U0005 to bill for the add-on payment. Labs that fail to meet the add-on payment criteria will receive only the $75 base pay rate.

The new payment policy "supports faster high throughput testing, which will allow patients and physicians to act quickly and decisively with respect to treatment decisions, physical isolation, and contact tracing," notes CMS Administrator **Seema Verma** in the announcement press release.

M&A Report: Exact Sciences Makes a Bold Double Play to Bolster Its Early Cancer Detection Capabilities

Although volume was light, October was a robust month for M&A deal making in terms of impact, especially in the cancer diagnostics space. The month started with the announcement of Invitae's acquisition of liquid biopsy testing firm ArcherDx for $1.4 billion and ended with a pair of strategic acquisitions of early cancer detection firms by Exact Sciences, one in liquid biopsies and the other in genomics technology.

Exact Science to Acquire Thrive Earlier Detection

Oct. 27 was a big day for Exact Sciences. In addition to publishing its Q3 2020 earnings, the Wisconsin-based producer of Cologuard and other cancer screening products announced that it has signed a binding agreement to acquire liquid biopsy test maker for $2.15 billion. **Deal terms:** Exact will pay $1.7 billion at closing, which is expected to take place in Q1 2021, 65 percent in Exact Sciences common stock and the 35 percent balance in cash. Thrive shareholders will also receive an addition $450 million in contingent payments based on the achievement of milestones in the development and commercialization of Thrive's CancerSEEK, a blood-based, screening test that interrogates genomic mutations in circulating tumor DNA (ctDNA) and cancer-associated protein markers in plasma to identify abnormalities associated with multiple cancers.

It's a bold move that comes just a year after Exact acquired fellow cancer technologies firm Genomic Health for $2.8 billion, bringing Cologuard and Genomic Health's Oncotype DX tests for predicting response to cancer treatments and quantifying recurrence risk under the same roof. CancerSEEK, which received FDA Breakthrough Device designation in June 2019 year for the detection of genetic mutations and proteins associated with pancreatic and ovarian cancers, could form the third leg of a formidable early cancer detection triad. Thrive is currently collaborating with Geisinger Health System on DETECT, a massive clinical trial assessing CancerSEEK's effectiveness on 10,000 healthy individuals.

Exact said that combining CancerSEEK with its own scientific platform, clinical organization and commercial infrastructure will help establish it as a leading competitor in blood-based, multi-cancer screening. "We have long respected the Thrive team for their rigorous

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scientific approach, having participated in both funding rounds as an investor," noted Exact Sciences Chariman and CEO **Kevin Conroy** in a statement.

It's not too hard to figure out why Thrive is such an appealing acquisition target. The previously obscure liquid biopsy maker made headlines last year by raising $110 million in a series A financing, breaking the previous record series A record of $100 million held by Grail (a company that's also in the process of being by Illumina from whence it was originally spun out). Last June, Thrive raised another $257 million in a series B round.

Exact Sciences Also Acquires Base Genomics

But Exact Sciences had one more blockbuster deal up its sleeve—the acquisition of epigenetics company Base Genomics for $410 million, which the company disclosed in its October 27 U.S. Securities and Exchange Commission filing. Created by the Ludwig Institute for Cancer Research Branch at the University of Oxford, Base Genomics has developed a technology enabling accurate analysis of DNA methylation and mutations in a single sample. Exact says it plans to leverage that technology to enhance all of its cancer diagnostics products across the continuum.

Invitae Acquires ArcherDx

The other big M&A news in October was the completion of Invitae's $1.4 billion acquisition of ArcherDx, a deal first announced in June. The addition of ArcherDx's tumor profiling and liquid biopsy technologies give Invitae the capacity to predict and monitor therapeutic response to its service offerings and move beyond germline cancer genetic testing. "Invitae is now well positioned to accelerate the utilization of genetic information throughout a cancer patient's journey," noted the statement from Invitae CEO **Sean George**. "Starting from risk profiling and diagnostic testing, moving to therapy optimization, monitoring and recurrence surveillance, Invitae can deliver the information needed to enable best-in-class personalized cancer care."

Invitae paid $325 million in cash and 30 million in company common shares upfront. ArcherDx shareholders will also receive up to 27 million more Invitae shares if certain milestones are met.

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

MERGERS, ACQUISITIONS & ASSET SALES

Acquiring Company	Target(s)	Deal Summary
Exact Sciences	Thrive Earlier Detection	• Price: Up to $2.15 billion, including $1.7 billion would be payable at closing, comprising 65% in Exact Sciences common stock and 35% in cash + $450 million contingent milestone payments • Status: Closing scheduled for Q1 2021 • Acquisition of liquid biopsy firm to ramp up Exact's early cancer detection capabilities
Exact Sciences	Base Genomics	• Price: $410 million • Status: Closed • Acquisition of epigenetics company developing methylation analysis methods for early cancer detection adds genomics piece to Exact's cancer detection portfolio
Invitae	ArcherDx	• Price: $1.4 billion, including $325 million cash + 30 million shares of Invitae common stock upfront + up to 27 million additional Invitae shares if milestones met • Status: Closed • Merger with cancer testing firm enables Invitae to expand its cancer service offerings beyond germline cancer genetic testing to include tumor profiling and liquid biopsy technologies for predicting and monitoring therapeutic response
Novacyt	IT-IS International	• Price: $13.1 million in cash • Status: Closed • Acquiring the exclusive manufacturer of the firm's q16 and q32 rapid PCR instruments near-patient testing of COVID-19 enables Novacyt to secure intellectual property associated with instruments and expand its core capabilities in instrument manufacturing and product offerings in mobile PCR devices
10x Genomics	ReadCoor	• Price: $350 million in cash and stock • Status: Expected to close by end of October • Acquisition of spinout from George Church's lab at Harvard Medical School and the Wyss Institute, which recently launched RC2 spatial multiomics platform based on fluorescent in situ sequencing technology
10x Genomics	Cartana	• Price: $41.2 million • Status: Closed in August • 10x Genomics acquires Sweden-based developer of in situ RNA analysis technology
Calibre Scientific	Lorne Laboratories	• Price: Undisclosed • Status: Closed • Acquisition of UK-based specialty manufacturer of blood grouping reagents and diagnostic test kits, and distributor of lab equipment, enzymes and biochemicals
Proteintech	ChromoTek	• Price: Undisclosed • Status: Closed • Addition of German manufacturer of single-domain antibodies

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M&A Report, *from page 11*

Acquiring Company	Target(s)	Deal Summary
Cyted		• Price: Undisclosed • Status: Closed • Cyted acquires UK digital pathology and clinical diagnostic lab services provider
Summa Equity	Sengenics	• Price: Undisclosed • Status: Closed • Private equity firm acquires functional proteomics firm that produces full-length folded protein arrays using its KREX protein folding technology
Geneyx Genomex	Toldot Genetics	• Price: Sellers, including biomedical informatics firm BATM Advanced Communications and minority shareholders receive 5 percent equity stake in Geneyx • Status: Closed • Israel-based developer of genomic analysis and interpretation software to integrate Toldot's TGex NGS analysis technology into its own platform
HNL Lab Medicine	NLM Laboratories	• Price: Undisclosed • Status: Closed • HNL acquires fellow lab services provider

Diagnostics Deals, *from page 1*

in-home and personalized treatments, to provide COVID-19 testing for travelers. While it's hardly the first such deal, the partnership is something of a game changer to the extent that the Vault Health test is a RT-PCR test run by the Rutgers Clinical Genomics Laboratory at RUCDR Infinite Biologics using technology that has received Emergency Use Authorization (EUA) from the FDA for use on saliva samples collected at home.

The way it works: Customers go to Vault Health's dedicated landing page and enter their JetBlue confirmation code to start the process and also receive a discount on the test. After receiving test materials by overnight mail, they collect their own saliva samples from home while a Vault Health supervisor looks on by Zoom video to ensure everything is done properly. The sample is then sent overnight to a lab, with results provided in 72 hours or less. There are no swabs or need for in-person interaction. The test, a modified version of a Thermo Fisher Scientific assay that received EUA in April, is highly accurate and capable of detecting fewer than 10 copies of SARS-CoV-2 genes per milliliter of saliva, according to Vault Health.

"We are so happy to be able to provide JetBlue customers peace of mind during their travels," said Vault Health founder and CEO **Jason Feldman** in a statement. "This saliva test is one of the most reliable and accurate COVID tests available in the country with fast turnaround time to results."

Other Airline-Lab COVID-19 Testing Arrangements

Other airlines offering COVID-19 testing to travellers seeking to avoid quarantine and self-isolation include:

United Airlines was the first to offer testing. But while the airline plans to expand the program to other airports, testing is currently limited to customers traveling form San Francisco International Airport to Hawaii. There are two test options:

- A $250 rapid Abbott ID NOW COVID-19 test performed by GoHealth Urgent Care at San Francisco International Airport on the day of travel; or
- An $80 mail-in test administered by Color that travelers must complete 72 hours before travel.

American Airlines has partnered with CareNow. The test options:

- A $150 in-person testing at designated CareNow urgent care locations, which are open every day and after-hours; or
- A $249 on-site rapid testing on the day of the flight administered by CareNow at DFW (Dallas Fort Worth) International Airport with results expected in 15 minutes on average.

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American has also entered a partnership with a second provider, LetsGetChecked, which allow passengers to order tests before flying from five locations, three of which are in Hawaii (cost: $129) and two in Costa Rica (cost $109).

Hawaiian Airlines has tabbed Worksite Labs to offer testing at labs near Los Angeles and San Francisco International airports, with more locations to come. Cost: $150 for day-of travel express service and $90 for results within 36 hours.

Alaska Airlines has partnered with Carbon Health to offer passengers in Seattle who are traveling to Hawaii testing at a downtown pop-up clinic that promises test results within two hours at the cost of $135.

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

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS

Partner 1	Partner(s) 2+	Deal Summary
Invitae	Pacific Biosciences	• Objective: Use long-read next-generation sequencing to develop diagnostic testing for epilepsy • Dynamic: Use single-molecule, whole-genome sequencing using PacBio's HiFi reads to large cohort of pediatric patients with epilepsy to develop comprehensive variant profiles for use in investigating genetic etiology of epilepsy
Microsoft	Pacific Biosciences + Children's Mercy Kansas City	• Objective: Improve diagnostic yield for rare disease sequencing • Dynamic: Children's Mercy to apply PacBio HiFi reads to difficult cases of rare pediatric disease • Microsoft to help build Azure cloud-based analysis solutions and data repository
Agilent Technologies	InterVenn	• Objective: Investigate glycoproteomic biomarkers for diseases common in Southeast Asia, such as cancer • Dynamic: Work to be done at Malaysian lab of InterVenn, firm created by California researchers to commercialize glycoproteomic analysis methods for ovarian, colorectal and other cancers

Partner 1	Partner(s) 2+	Deal Summary
Summit Biolabs	Colorado Center for Personalized Medicine (CCPM)	• Objective: Develop saliva-based liquid biopsy tests for head and neck cancer, COVID-19, and other viral diseases • Dynamic: Summit Biolabs to integrate CCPM's research biobank with personalized genomic information to create the assays
Inspirata	Carebox Healthcare Solutions	• Objective: Launch new product providing hospitals and oncologists information on matching their cancer patients with clinical trials • Dynamic: Inspirata to use its informatics technologies to extract data from pathology reports and electronic health records to create patient-specific clinical and genomic data profiles that will be combined with Carebox's system for matching eligibility criteria from clinical trial databases with patients' health and genomic data to identify potentially relevant studies for them
PierianDx	Pillar Biosciences	• Objective: Create product to generate an "out-of-the-box" clinical genomic report specific to each assay • Dynamic: PierianDx to integrate Pillar Biosciences PiVAT cancer bioinformatics pipeline into its core technology platform • Pillar to market PieranDx clinical genomic reports along with its own cancer profiling assays
Twist Bioscience	Neogene Therapeutics	• Objective: Develop personalized chimeric antigen receptor (CAR) T cell therapies and T cell receptor (TCR) therapies for cancer patients • Dynamic: Broad strategic partnership in which Twist Biopharma to create a specialized TCR library for Neogene with goal of discovering engineered TCRs against two specified T cell targets for future Neogene personalized T cell therapies

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Diagnostics Deals, *from page 15*

Partner 1	Partner(s) 2+	Deal Summary
Exact Sciences	Pfizer	• Objective: Promote Exact's Cologuard colorectal cancer screening test • Dynamic: Extension of current agreement for Pfizer to continue to provide marketing and related support for Cologuard and help Exact educate patients, physicians and health systems about the product • Pfizer to also provide sales and marketing support through end of 2022 and health system support through end of 2021 • Exact to compensate Pfizer based on amount of services provided, along with additional fixed and performance-related fees
CIC Health	Ariadne Labs	• Objective: Expand and streamline access to SARS-CoV-2 testing in US • Dynamic: Assurance Testing Alliance (ATA) to handle logistics and operations required to connect labs with schools, elder care settings, employers, and other groups needing regular SARS-CoV-2 testing • ATA to also offer technology platform organizations can use to offer testing to their employees
IsoPlexis	Yale University	• Objective: Develop assays for COVID-19 • Dynamic: Use IsoPlexis' IsoLight system to identify markers of patient immune response to the virus for use in developing therapies and vaccines for COVID
Oncocyte	Fondazione Michelangelo (Milan, Italy)	• Objective: Evaluate Oncocyte's DetermaIO test as a therapy response predictor in NeoTRIPaPDL1 trial • Dynamic: DetermaIO is a tissue-based gene expression assay that evaluates signals associated with the tumor immune microenvironment and stratifies patients by likelihood of responding to immunotherapy

Partner 1	Partner(s) 2+	Deal Summary
JetBlue Airways	Vault Health	• Objective: Provide COVID testing to passengers planning to travel who must prove they tested negative for the virus to avoid quarantine and get into the country or state • Dynamic: Customers to administer at-home saliva test via an online video through Vault while a supervisor ensures the sample is properly taken • Sample then sent overnight to a lab, with results provided in 72 hours or less
Sema4	Janssen	• Objective: Identify patients for enrollment in Janssen oncology clinical trials • Dynamic: Sema4 to give Janssen access to its genomics testing capabilities and Centrellis health intelligence platform
Genosity	Olink Proteomics	• Objective: Strategic services and collaboration agreement for US • Dynamic: Genosity to offer Sweden-based Olink's proximity extension assay technology at its CLIA lab and include it in its Genosity Integrated Genomics Toolkit software • Enables Genosity to ramp up its product offerings and Olink to expand into US market for protein biomarker discovery services
LabCorp	Genfit	• Objective: Commercialize Genfit's NIS4 technology for patients with non-alcoholic steatohepatitis (NASH) • Dynamic: Exclusive 5 year licensing agreement giving LabCorp access to the NIS4 technology

DISTRIBUTION, SALES & MARKETING AGREEMENTS

Product Owner	Distributor	Deal Summary
Mawi DNA Technologies	Nucleus Biotech	• Products: Mawi DNA's iSWAB biosampling products • Territory: Germany, Austria, Switzerland

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Diagnostics Deals, *from page 17*

Product Owner	Distributor	Deal Summary
Proteomics International Laboratories	Medical Horizons SRL	• Products: Proteomics' ELISA-based Promarker D (IA) diabetic kidney disease immunoassay • Territory: Italy • Exclusive
Toda Pharma	Genomic Vision	• Products: Toda's Toda Coronadiag+ and Coronadiag Ag, both of which are rapid diagnostic tests for SARS-CoV-2 • Territory: Undisclosed
RevoluGen	Welgene Biotech	• Products: RevoluGen's Fire Monkey/Fire Flower High Molecular Weight DNA (HMW-DNA) extraction and purification product • Territory: Taiwan • Non-exclusive
Agendia	PathoNext	• Products: Agendia's MammaPrint BluePrint Breast Cancer Recurrence and Molecular Subtyping tests • Territory: Germany
CellSafe	Dynasty Castle Investments	• Products: CellSafe's LAMPlex RT-qLAMP COVID-19 Detection Assay • Territory: Portugal and 6 unspecified African countries
BillionToOne	Swift Biosciences	• Product: BillionToOne's qSanger-COVID-19 assay test kit • Territory: Undisclosed • Exclusive

LICENSES

Licensor	Licensee	Deal Summary
Quanterix	Abbott Laboratories	Abbott gets non-exclusive license to use Quanterix's bead-based technology patents for diagnostics applications for $10 million upfront + royalties + milestone payments
Harvard's Wyss Institute for Biologically Inspired Engineering	Agile Biodetection	Non-exclusive, royalty-free licensing agreement enabling Agile to use Wyss' nasopharyngeal swab and toehold switch technologies to SARS-CoV-2 diagnostics

Licensor	Licensee	Deal Summary
Chronix Biomedical	Oncocyte	Oncocyte licenses Chronix's blood-based copy number instability testing technology and will use its laboratory network in Germany to accelerate EU market launch of Oncocyte's DetermaRx

SUPPLY, SERVICE & TESTING AGREEMENTS

Supplier/Servicer	Client/User	Deal Summary
LabCorp	Infirmary Health	LabCorp to provide lab management, phlebotomy, logistics services and reference testing to Alabama-based health network