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IN THIS ISSUE

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DX Earnings Report: Q3 Creates the Perfect Storm of Sustained COVID-19 Tailwinds and Diminishing Headwinds

July through September 2020 was a remarkable quarter for most diagnostics firms. In fact, it was the closest thing to a perfect storm for earnings. Pandemic tailwinds drove massive revenues for firms that had made the pivot into COVID-19 testing; meanwhile, the momentary lull in case rates allowed for firms that were buffeted by declines in baseline testing in Q2 and the end of Q1 to get back to almost pre-pandemic levels. The bad news for the latter group is that the surge in COVID-19 cases will make that formula totally unsustainable in Q4.

Continued on page 2

HHS to FDA: Resume EUA Review of COVID-19 LDTs, And Do It Fast

The controversy over FDA Emergency Use Authorization (EUA) of laboratory developed tests (LDTs) for COVID-19 is on high boil once more. A month after the agency announced it would no longer review such tests, the Department of Health and Human Services (HHS) has countermanded that decision, ordering the FDA to resume LDT EUA applications and do it in a "timely manner." The new HHS mandate is the latest and perhaps most decisive twist in what has become a somewhat bizarre battle within the administration over regulation of LDTs that has sparked up during the public health emergency.

The Controversy Over COVID-19 LDTs

Some of the earliest, most innovative and important new COVID-19 tests to receive EUA in the early days of the

Continued on page 22

DX Earnings Report, *from page 1*

Almost All Firms Experience Positive Growth

Before the pandemic began, DX earnings were on a long-term upward trajectory with gainers outnumbering decliners at a rough rate of 3 to 1. COVID-19 came too late in Q1 to make a dent in earnings. But things came home to roost in Q2 2020, with decliners leading gainers 29 to 12, including testing giants Abbott, Agilent, Becton Dickinson, LabCorp, Quest, Roche, and Siemens Healthineers.

But the Q3 turnaround is even more dramatic, with 36 of 41 firms posting growth, including almost all of the companies that experienced losses in the previous quarter. Bruker, Illumina, Myriad Genetics, Oxford Immunotec, and Siemens Healthineers finished the quarter with declines.

Gains Are Greater than Expected

Growth was not only almost universal but way higher than expected, with only two firms failing to meet their Wall Street targets—NeoGenomics and Pacific Biosciences. Most firms not only exceeded but annihilated their earnings targets for the quarter. Notable examples:

Companies Significantly Exceeding Third Quarter Wall Street Revenues Targets

Company	Q3 Wall Street Target	Q3 Actual Revenues
Abbott	$8.51 billion	$8.85 billion
Bio-Rad Laboratories	$570.6 million	$647.3 million
Danaher	$5.51 billion	$5.88 billion
Exact Sciences	$337.4 million	$408.4 million
Fulgent Genetics	$48.5 million	$101.7 million
LabCorp	$3.63 billion	$3.90 billion
Perkin Elmer	$841.2 million	$964.0 million
Thermo Fisher	$8.52 billion	$7.65 billion

Nor were the gaudy gains confined to the top line. Firms with eye-popping earnings per share for the quarter included:

- Bio-Rad Laboratories: Adjusted EPS of $3.00 vs. $1.80 Wall Street target;
- Fulgent Genetics: $2.88 vs. $0.55;
- Hologic: $2.07 vs. $1.22;
- LabCorp: $8.41 vs. $5.25;
- PerkinElmer: $2.09 vs. $1.50;
- Qiagen: $5.78 vs. $4.75;

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- Quest: $4.31 vs. $3.73; and
- Thermo Fisher: $5.63 vs. $4.31.

Takeaway

Criticism of diagnostics companies reaping massive earnings from the pandemic are incredibly misplaced and overlook the herculean efforts firms have made to meet unprecedented demands for COVID-19 testing. In the early days of the public health emergency, these firms had the foresight to recognize the opportunity and develop innovative tests for coronavirus. These innovators included not only firms in immunoassays and molecular testing, but genomics testing firms like Exact Sciences, Fluidigm Genetics and Quidel. For other firms like Natera, the formula has been to remain in their core non-COVID-19 space but adapt their businesses to remote ordering and other logistical challenges posed by the pandemic. Regrettably, the COVID-19 headwinds will be back in Q4 to wreak destruction on the revenues of companies relying on baseline, routine and hospitalization-associated testing, while serving as significant tailwinds to COVID-19 testing firms.

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Diagnostics Earning Reports for Q3 (period ended Sept. 30, 2020)
(At least $10 million in sales)

COMPANY	FY 2020 Q3			DX Segment Performance
	Total Revenue (vs. Wall Street)	YOY Revenues	EPS (vs. Wall Street)	
Abbott Laboratories	$8.85 billion ($8.51 billion)	+10% (+11% organic)	Adjusted +$0.98 (+$0.90)	DX up 38% to $2.64 billion, even though core DX flat at $1.18 billion, driven by massive demand for COVID tests, including 313% increase in molecular to $458 million and 83% increase in rapid diagnostics to $875 million; point of care drops 10% to $131 million
Adaptive Biotech	$26.3 million ($23.6 million)	+1%	Net -$.27 (-$.28)	Sequencing down 3% to $11.3 million even though test volume for ClonoSeq increased 58% with 4,023 tests delivered; developmental revenues up 5% to $15.0 million

Continued on page 4

DX Earnings Report, *from page 3*

COMPANY	FY 2020 Q3			DX Segment Performance
	Total Revenue (vs. Wall Street)	YOY Revenues	EPS (vs. Wall Street)	
Agilent Technologies (FY 4Q)	$1.48 billion ($1.40 billion)	+8%	Adjusted +$0.98 (+$0.93)	Diagnostics and Genomic Group up 9% to $294 million, Life Sciences and Applied Markets up 8% to $671 million; CrossLab group up 11% to $518 million
Becton Dickinson (FY Q4)	$4.78 billion ($4.48 billion)	+4%	Adjusted +$2.79 (+$2.52)	Growth driven by COVID-19 testing, including newly launched Veritor assay and Veritor and BD Max platforms; COVID testing generates $440 million; routine testing rebounds from Q3 but remained below pre-pandemic levels
Berkeley Lights	$18.2 million ($15.3 million)	+16%	-$0.16 (-$0.20)	Product revenue up 7% to $14.1 million, driven by $12.4 million in direct platform and instruments sales
BioMérieux	$934.2 million	+21% (+27% organic)		Clinical applications up 27% to $818.47 million, with over 100% growth in molecular and immunoassays more than offsetting 9% decline in microbiology
Bio-Rad Laboratories	$647.3 million ($570.6 million)	+15%	Adjusted +$3.00 (+$1.80)	Life Sciences up 50% to $324 million driven by PCR and Droplet Digital PCR products in response to COVID-19, which also drove Clinical DX down 6% to $322.2 million
Bio-Techne (2021 FY Q1)	$204.2 million ($185.0 million)	+11%	Adjusted +$1.43 (+$1.09)	DX & Genomics up 18% to $50.1 million driven by RNAscope RNA in situ and hybridization products; Protein Sciences up 10% to $154.4 million due to reopening of biopharma and academic sites after COVID shutdowns

COMPANY	FY 2020 Q3			DX Segment Performance
	Total Revenue (vs. Wall Street)	YOY Revenues	EPS (vs. Wall Street)	
Bruker	$511.4 million ($483.7 million)	-2%	Adjusted +$0.35 (+$0.31)	CALID group up 8% to $171.3 million, including $8.5 million in molecular SARS-CoV-2 testing, 6% increase in BioSpin to $152.1 million, which offset 13% decline in Bruker Nano to $147.1 million and 17% decline in BEST to $43.8 million
CareDx	$53.4 million ($53.0 million)	+58%	+$0.10 (-$0.06)	Testing services up 61% to $45.5 million driven by 65% increase in AlloSure and AlloMap sales; Products sales up 29% to $5.4 million; Digital and other revenues up 79% to $2.5 million
Castle Biosciences	$15.2 million $15.0 million	+3%	-$0.23 (-$0.11)	Decision Dx-Melanoma test reports up 7% to 4,404 due to COVID respite
Danaher	$5.88 billion ($5.51 billion)	+35%	Adjusted +$1.72 (+$1.36)	DX up 18% to $1.89 billion, driven by demand for Beckman Coulter and Cepheid COVID testing, with Cepheid experiencing over 100% core growth after shipping 7 million tests, which is expected to rise to 8 million in Q4; Life Sciences up 72% to $2.92 billion, including newly acquired Cytiva
Exact Sciences	$408.4 million ($337.4 million)	+87%	-$1.46	2% decline in screening revenues to $214.6 million, including Cologuard, more than offset by $91.6 million in precision oncology revenues from newly acquired Paradigm Diagnostics and $102.2 million in COVID testing, nearly tripling $34.6 million in COVID tests in Q2

Continued on page 6

DX Earnings Report, *from page 5*

COMPANY	FY 2020 Q3			DX Segment Performance
	Total Revenue (vs. Wall Street)	YOY Revenues	EPS (vs. Wall Street)	
Fluidigm	$39.9 million ($32.5 million)	+50%	Adjusted +$0.07 (-$0.20)	Pivot to COVID testing enables microfluidics and cytometric testing firm to hold pandemic losses to mass cytometry to less than Q2 levels (down 3% to $15.5 million) and massively grow microfluidics products by 88% to $20.2 million with nearly 800,000 COVID tests and sales of 30 Biomark HD instruments
***Fulgent Genetics**	$101.7 million ($48.5 million)	+1,000%	Adjusted +$2.88 (+$0.55)	Adaptation of genetic testing platform for COVID testing drives massive year-over-year increase in billable tests from 20,697 to 1.04 million
GenMark Diagnostics*	$42.6 million ($39.3 million)	+104%	Net -$0.05 (-$0.06)	Pandemic drives 187% increase in ePlex revenues to $38 million with 70 new analyzer systems placed during quarter, raising global total 47% to 720
Guardant Health	$74.6 million ($65.9 million)	+23%	Net -$0.78 (-$0.38)	Revenues return to nearly pre-pandemic levels with oncology up 16% to $60.4 million; development services up 65% to $14.2 million driven by new companion Dx products for biopharma
Hologic (FY Q4)	$1.35 billion ($1.12 billion)	+56%	Adjusted +$2.07 (+$1.22)	Total DX up over 300% to $939 million driven by over 500% growth in molecular diagnostics to $818.9 million due to demand for COVID tests on Panther and Panther Fusion instruments; decline in non-COVID tests, including 48% in blood screening to $8.7 million, and 6% decline in cytology and perinatal revenues to $111.4 million

COMPANY	FY 2020 Q3			DX Segment Performance
	Total Revenue (vs. Wall Street)	YOY Revenues	EPS (vs. Wall Street)	
Illumina	$794 million ($715.9 million)	-12%	+$1.02 (+$0.77)	Sequencing consumables down 5% to $500 million, offset by 3% growth in mid-throughput systems, with $109 million in total sequencing systems; Sequencing services 28% to $99 million; Microarray down 16% to $88 million
Invitae	$68.7 million ($59.7 million)	+22%	Non GAAP -$0.62 (-$0.66)	Test revenues up 21% to $67.3 million with test volumes bouncing back due to easing of COVID conditions; Samples acquisitioned up 32% to 170,000
LabCorp	$3.90 billion ($3.63 billion)	+33% (+32% organic)	Adjusted +$8.41 (+$5.25)	Diagnostics up 54% to $2.70 billion driven by 54% increase in COVID testing (vs Q2) and recovery in baseline testing, which was down only 2% year over year; PAMA price cuts responsible for 1% decline
Luminex	$106.1 million ($105.0 million)	+35%	Net -$0.04 (-$0.20)	Assays up 89% to $55.6 million driven by COVID molecular testing, which offset declines in clinical tools and life sciences; cytometry down but to a lesser extent than in Q2
Meridian Bioscience (FY Q4)	$64.2 million ($59.6 million)	+26%	Adjusted +$0.19 (+$0.14)	Molecular reagents, including COVID, up over 400% to $22.7 million, which offsets overall 11% in DX revenues to $29.8 million, including 23% decline in molecular tests to $6.1 million, and 8% decline in non-molecular assays to $25.2 million; immunological reagents down 1% to $11.6 million

Continued on page 8

DX Earnings Report, *from page 7*

COMPANY	FY 2020 Q3			DX Segment Performance
	Total Revenue (vs. Wall Street)	YOY Revenues	EPS (vs. Wall Street)	
Myriad Genetics (FY 2021, Q1)	$145.2 million ($135.2 million)	-22%	Adjusted -$0.15 (-$0.30)	Testing volumes recover to 90% of pre-pandemic levels by end of Sept. but still down across all segments due to COVID-19, with molecular DX down 21% to $135.7 million, including 23% drop in hereditary cancer ($80.6 million), 48% decline in GeneSight ($11.9 million), 17% decline in Vectra ($9.1 million), 2% drop in Prolaris ($6.4 million);
NanoString Technologies	$31.8 million ($28.7 million)	+4%	Net -$0.56 (-$0.60)	Product + service pro forma revenues up 22% due to acquisition of Prosigna breast cancer test; consumables down 11% to $13.7 million; Instruments up 60% to $12.9 million, including $7.5 million from newly launched GeoMx system and $5.4 million from nCounter
Natera*	$98.1 million ($87.2 million)	+26%	Net -$0.72 (-$0.69)	Third outstanding quarter in a row, with 39% increase in products to $93.3 million; 31% more tests processed at 200,200; lab has minimized disruption to core reproductive health business, including Panorama and Horizon assays, thanks to improvements to remote ordering capabilities
NeoGenomics	$125.4 million ($126.2 million)	+20%	Adjusted +$0.06 (+$0.04)	Core oncology testing bounces back with overall test volume up 2% to 255,458 tests performed, requisitions up 2% to 147,518, but revenue per test down 3% to $359

COMPANY	FY 2020 Q3			DX Segment Performance
	Total Revenue (vs. Wall Street)	YOY Revenues	EPS (vs. Wall Street)	
Opko Health	$428.1 million ($376.4 million)	+87%	Pro forma +$0.04 (+$0.05)	111% increase in services revenues to $382.5 million, due to COVID testing with BioReference Lab processing over 3.5 million PCR and 300,000 antibody tests, which more than offsets drops in genomic and clinical testing; product revenues up 10% to $28.7 million
OraSure Technologies	$48.0 million ($41.7 million)	+33%	Net +$0.01 (-$0.07)	Products and services up 32% to $46.7 million, driven by 79% growth in molecular solutions to $31.7 million and $18.4 million in sales for molecular SARS-CoV-2 sample collection devices, which more than offset 38% decline in genomics to $8.5 million and infectious disease testing products, including 3% decline in microbiome to $1.8 million
Oxford Immunotec	$19.4 million ($18.7 million)	-8%	Net -$0.01 (-$0.05)	Tuberculosis and other testing volumes recover but remain at below pre-pandemic levels in all geographic regions
Pacific Biosciences	$19.1 million ($20.4 million)	-13%	Net -$0.14 (-$0.13)	Products down 15% to $15.7 million, Services down 3% to $3.3 million, as pandemic aggravates pre-existing problems
PerkinElmer	$964.0 million ($841.2 million)	+36%	+$2.09 (+$1.50)	Follows Q2 recovery with massive Q3, driven by 93% growth in DX to $540.4 million, with COVID PCR tests and RNA extraction solutions each contributing over $100 million—although serology testing for COVID was below Q2 levels; Applied genomics up 360%; "modest declines" in reproductive health

Continued on page 10

DX Earnings Report, *from page 9*

COMPANY	FY 2020 Q3			DX Segment Performance
	Total Revenue (vs. Wall Street)	YOY Revenues	EPS (vs. Wall Street)	
Qiagen*	$483.8 million ($462.8 million)	+26%	Adjusted +$5.78 (+$4.75)	23% growth in consumables to $420 million driven by unprecedent demand for COVID testing cartridges, including 29% increase in molecular diagnostics to $237 million, as well as spikes in sales of reagents + RNA extraction kits; Instruments up 57% to $67 million; QuantiFerron-TB tests fall 20% to $53 million
Quanterix	$31.4 million ($14.9 million)	+111%	Not reported	One-time recognition of $11.2 million license payment from Abbott drives revenues increase and belies more modest 9% growth in Products to $11.7 million; Services up 56% to $6.6 million; Company expects 2H rebound to continue into Q4
***Quest Diagnostics**	$2.79 billion ($2.73 billion)	+43%	Adjusted +$4.31 (+$3.73)	Test volume down 5% but partly offset by expanded COVID testing capacity with 9.9 million molecular + 1.5 million serology tests performed, enabling Quest to return $138 million in CARES Act payments received
Quidel	$476.1 million ($450.4 million)	+276%	Adjusted +$5.78 (+$4.75)	Molecular DX up from $4.7 million to $63 million, including $57.8 million in Lyra SARS-CoV-2 test revenues; Rapid immunoassays up from $42.5 million to $337 million, including $317.9 million from Sofia SARS Antigen test; Cardio immunoassays fall 3% to $64.8 million due to decline in hospital visits; Specialized DX down 10% to $11.2 million

COMPANY	FY 2020 Q3			DX Segment Performance
	Total Revenue (vs. Wall Street)	YOY Revenues	EPS (vs. Wall Street)	
Roche Diagnostics	$4.23 billion (DX revenues)	+18%	Not reported	Molecular DX up 67% to $2.86 billion, offsetting declines of 1% in tissue DX ($882.67 million) and 10% decline in diabetes care ($1.40 billion)
Siemens Healthineers (FY Q4)	$1.25 billion (DX revenues)	-6%	Adjusted +$0.58	Modest gains in COVID reagent products not nearly enough to offset huge losses in routine testing
10x Genomics	$71.8 million ($61.2 million)	+17%	Net -$0.65 (-$0.30)	Rebounds from Q2 declines. 22% increase in consumables to $60.6 million; Instruments down 7% to $9.7 million despite higher average prices for Chromium Connect platform sales; Service up 46% to $1.6 million
Thermo Fisher	$8.52 billion ($7.65 billion)	+36%	Adjusted +$5.63 (+$4.31)	23% of total revenues ($2.0 billion) come from COVID and continued recovery of baseline testing fuels another massive quarter; Life Sciences up 101% to $3.42 billion; Specialty DX up 63% to $1.43 million driven by COVID testing; Lab products + services up 19% (16% organic) to $3.11 billion driven by pharma services and research + safety, including PPE sales
Veracyte	$31.1 million ($23.9 million)	Flat	Net -$0.08 (-$0.21)	Genomic testing volumes up 3%, including increase of 6% for Affirma and 37% decline in Percepta
Waters	$593.8 million ($546.5 million)	+3%	Non-GAAP +$2.16 (+$1.93)	Pharma up 5%, Industrial up 5%, Academic and government sales down 8%

Bold face: Companies that met or exceeded average or consensus Q3 Wall Street revenue estimates

Italics: Companies that missed average or consensus Q3 Wall Street revenue estimates

*: Companies that raised their revenue or EPS guidance during Q3

FDA WATCH

Lucira Health Secures First EUA for Fully At-Home COVID-19 Testing Kit

Although the FDA has previously authorized COVID-19 diagnostic tests for at-home sample collection, it had never before granted Emergency Use Authorization (EUA) for an all-in-one diagnostic kit that allows people to test themselves for COVID-19 in their own home. But with cases surging, the agency made history on Nov. 17 by granting EUA to such a product from Emeryville, California-based Lucira Health. "A test that can be fully administered entirely outside of a lab or healthcare setting has always been a major priority for the FDA to address the pandemic," noted **Jeff Shuren**, director of FDA's Center for Devices and Radiological Health, said in a statement.

The Lucira At-Home Test Kit

The Lucira COVID-19 All-in-One Test Kit is a single use test is based on loop-mediated isothermal amplification (LAMP) that operates at ambient temperatures to detect SARS-CoV-2 RNA from self-collected swab samples. Physicians prescribe the test for patients age 14 or above that they suspect have the virus. The assay runs on a handheld battery-powered device that looks like a thermometer and provides a result via LED readout in 30 minutes or less. The EUA also allows for use of the test at the point of care in doctor's offices, hospitals, urgent care and other CLIA-waived settings on samples collected by a healthcare provider.

According to the FDA, the Lucira test achieved 94 percent sensitivity and 98 percent specificity in a community testing study comparing the assay to an FDA-authorized SARS-CoV-2 test with known high sensitivity. Lucira adapted the test from a prototype it originally created for use as a flu test before pivoting in response to the pandemic.

Lucira says that it expects the test, which costs $50, to be available nationwide by the early spring. Lucira also plans to file for FDA approval to allow the test to be prescribed through a telehealth visit, with the kit to be delivered by mail. "This new testing option is an important diagnostic advancement to address the pandemic and reduce the public burden of disease transmission," noted FDA Commissioner **Stephen Hahn** in a statement.

LabCorp May Be Next

Meanwhile, testing giant LabCorp may soon up the ante by launching an at-home diagnostic of its own capable of detecting not only COVID-19 but also influenza and respiratory syncytial virus from a single sample making it perfectly suited for flu season. The new product, which will be offered through LabCorp's Pixel service, will be an at-home version of the combined test currently provided in doctors' offices, hospitals and other point of care settings.

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Here are the other key new FDA EUAs and clearances announced from late October through late November:

New FDA Emergency Use Authorizations (EUAs) & Approvals

Manufacturer(s)	Product
Hologic	Clearance for HIV-1 viral load monitoring Aptima HIV-1 Quant Dx assay, first dual-claim assay for both diagnosis and viral load monitoring in US
Lucira Health	EUA for Lucira COVID-19 All-in-One Test Kit, first fully at-home test authorized for COVID-19
GenScript Biotech	EUA for cPass SARS-CoV-2 Neutralization Antibody Detection Kit, first SARS-CoV-2 neutralizing antibody test to receive EUA
Foundation Medicine	Clearance for FoundationOne Liquid CDx test as companion diagnostic with olaparib (AstraZeneca and Merck's Lynparza)
Quansys Biosciences	EUA for Q-Plex SARS-CoV-2 Human IgG (4 Plex) immunoassay
DNA Genotek	EUA for ORAcollect RNA ORE-100 and ORAcollect RNA OR-100 saliva collection devices for SARS-CoV-2 testing
LabCorp	Reissued EUA for COVID-19 RT-PCR Test changing type of samples that can be used for pooled testing
Color	Reissued EUA for loop-mediated isothermal amplification-based SARS-CoV-2 test allowing use on self-collected samples
PerkinElmer	Reissued EUA for New Coronavirus Nucleic Acid Detection Kit allowing use for pooled samples
Roche	Clearance for Cobas EGFR Mutation Test v2 as companion diagnostic for non-small cell lung cancer therapies
Agena Bioscience	EUA for MassArray SARS-CoV-2 Panel
Merck	Accelerated clearance for pembrolizumab (Keytruda) plus chemotherapy as treatment for locally recurrent, unresectable, or metastatic triple-negative breast cancer patients with high PD-L1-expressing tumors

New CE Marks & Global Certifications

Notable European CE certifications announced during the period:

NEW CE MARKINGS IN EUROPE

Manufacturer(s)	Product(s)
Cepheid	Xpert Xpress SARS-CoV-2/Flu/RSV rapid molecular diagnostic test
Zymo Research	Quick-DNA/RNA Viral MagBead Kit
Zymo Research	Quick SARS-CoV-2 Multiplex Kit
PerkinElmer	SARS-CoV-2 Real-time RT-PCR assay for use on saliva and sample pooling

Continued on page 14

FDA Watch, *from page 13*

Manufacturer(s)	Product(s)
Euroimmun (PerkinElmer)	Anti-SARS-CoV-2 QuantiVac ELISA test to quantify IgG antibodies
Tempus	xT, cancer genomic sequencing assay
PathoFinder	RespiFinder 2Smart kit for SARS-CoV-2 and Middle East respiratory syndrome-related coronavirus (MERS-CoV) testing
PathoFinder	RealAccurate Quadriplex (RAQ) Flu/COVID-19 PCR kit
Siemens Healthineers	Quantitative SARS-CoV-2 IgG antibody test
Bioneer	AccuPower RV1 Real-Time RT-PCR Kit and AccuPower RV1 Multiplex Kit combination tests
Hologic	Genius Digital Diagnostics cytology platform for cervical cancer screening
Qiagen	NeuMoDx Flu A-B/RSV/SARS-CoV-2 Vantage Test to identify and differentiate between seasonal respiratory infections and COVID-19
Co-Diagnostics	Logix Smart SARS-CoV-2 multi-gene test, which detects both RdRp and E genes of virus
Co-Diagnostics	Logix Smart ABC assay, combination test for influenza A/B and SARS-CoV-2
Ortho Clinical Diagnostics	Vitros Immunodiagnostic Products TSH3 reagent pack and calibrator
Biocartis	Idylla SARS-CoV-2 assay
Beckman Coulter	Access SARS-CoV-2 IgM assay
Credo Diagnostics Biomedical	VitaPCR Influenza A&B/SARS-CoV-2 combination test

Other international clearances announced during the period:

Manufacturer(s)	Country(ies)	Product(s)
Sysmex	Japan	HISCL SARS-CoV-2 Ag Reagent test kit
Becton Dickinson	Canada	Health Canada approval for rapid point-of-care SARS-CoV-2 antigen test for use on BD Veritor Plus System

DX Deals: Fitness Wearables Makers Look to Apply Technology for Consumer-Based Diagnostics

Could the Fitbit, smartwatch and other wearable devices be a key to resolving the current COVID-19 testing and other diagnostic challenges? Momentum for applying wearables health and wellness measuring technology for purposes of widespread, consumer-based diagnostics has been building rapidly even before the pandemic, as is the scientific evidence to support the validity of the concept. Were it to succeed, the approach of wedding consumer wearables to COVID-19 detection and differentiation could go a long way in resolving the current rapid testing challenge.

Wearables and COVID-19 Diagnosis

The idea of using Fitbit and other wearable devices for diagnostic purposes is nothing new. And a new study by Scripps Research Translational Institute published in *Nature* suggests that such information may include whether we have COVID-19. Conducted by researchers from the Digital Engagement and Tracking for Early Control and Treatment (DETECT), the *Nature* study is one of the first to consider wearables for COVID-19 diagnosis. The researchers' aim was to investigate whether the addition of individual changes in sensor data to symptom data can be used to improve our capability to identify COVID-19-positive versus COVID-19-negative cases among participants who self-reported symptoms.

The Fitbit Study

Wearable makers have also been active in exploring the diagnostic potentials of their products. Before the pandemic, San Francisco-based Fitbit applied its own tracking health and wellness metrics technology to develop an algorithm to detect breathing rate, resting heart rate and other factors. The original intention was to alert users to signs of flu infection. But when the public health crisis began, Fitbit pivoted and adapted the concept for COVID-19.

The algorithm was studied only in a retrospective setting, and there was a need for a prospective study to validate it in a real-world setting. Accordingly, Fitbit recently announced that it is collaborating with Northwell Health's Feinstein Institutes for Medical Research on a study to validate the Fitbit COVID-19 early detection algorithm. The Fitbit study is supported by a $2.5 million award from the U.S. Department of Defense through the medical technology enterprise consortium. The award is part of the consortium's efforts to keep military personnel healthy by detecting the virus before symptoms emerge.

Several thousand frontline and custodial Northwell staffers are expected to participate in the study. Once the study is initiated, enrolled Northwell

Continued on page 16

DX Deals:, *from page 15*

employees will be given a Fitbit smartwatch. Upon notification of signs of potential illness, they will be given COVID-19 tests for verification.

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

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS

Partner 1	Partner(s) 2+	Deal Summary
Bio-Me	Siolta Therapeutics	• Objective: Develop rapid diagnostic test for newborns at risk of developing allergy and asthma later in life • Dynamic: Siolta to Bio-Me samples and insights into key criteria
OneOncology	Genentech	• Objective: Bring comprehensive genomic profiling to community oncology setting • Dynamic: Genentech to launch new basket trial enrolling patients treated throughout the OneOncology Research Network (OneR)
Qiagen	TScan Therapeutics	• Objective: Develop T cell-based lab tests to detect exposure to SARS-CoV-2 using discoveries from TScan's high-throughput T-cell receptor (TCR)/target discovery platform • Dynamic: Qiagen gets option to license rights and intellectual property for TScan's discovered immunodominant T-cell targets, associated sequences and data for development and commercialization of diagnostic tests • Qiagen also gets right to further evaluate TScan discoveries
Qiagen	BioNTech	• Objective: Develop tissue-based companion diagnostic to identify patients with squamous cell head and neck cancer caused by specific HPV infections eligible for BioNTech's investigational cancer treatment BNT113 • Dynamic: Assay detecting presence of specific HPV genotypes to be developed on Qiagen's real-time PCR-based RGQ MDx platform

Partner 1	Partner(s) 2+	Deal Summary
Ginkgo Bioworks	Access Bio	• Objective: Distribution of rapid COVID-19 antigen tests • Dynamic: Ginkgo to provide Access Bio undisclosed amount of funding to expand manufacturing capacity for tests • Ginkgo to offer at least 10 million antigen test kits through its Concentric by Ginkgo service
Aspira Women's Health	Baylor Genetics	• Objective: Develop early detection test for ovarian cancer • Dynamic: Aspira to leverage its experience in recruitment of patient samples and assay development
Agendia	Paige	• Objective: Develop products to enable faster access to predictive and prognostic information for breast cancer care and treatment • Dynamic: Integrate Paige's cloud-based Paige Platform with genomic information from Agendia's MammaPrint and BluePrint diagnostic tests
NanoString Technologies	Oregon Health & Science University	• Objective: Develop GeoMx Digital Spatial Profiler-based protein assays for breast cancer • Dynamic: OHSU pathologists to design a new GeoMx protein assay with up to 30 targets, including existing diagnostic markers and novel biomarker candidates and clinically validate assay for potential use as laboratory-developed test
Tempus	Yale School of Public Health	• Objective: Refine saliva-based test for SARS-CoV-2 • Dynamic: SalivaDirect tests uses dualplex RT-qPCR to detect SARS-CoV-2 RNA in saliva samples without need for special types of swabs or collection devices, or a separate nucleic acid extraction step • Test has EUA from FDA but parties to further develop it to enable at-home sample collection and combination testing for SARS-CoV-2 and influenza

Continued on page 18

DX Deals:, *from page 17*

Partner 1	Partner(s) 2+	Deal Summary
Tempus	Janssen Research & Development	• Objective: Develop predictive machine-learning model to improve enrollment in biomarker-driven oncology clinical trials for Janssen R&D • Dynamic: Janssen looking for method to speed up identification of patients with specific tumor features that match the requirements of trials
Myriad Genetics	Burning Rock Biotech	• Objective: Expand Myriad's myChoice CDx in China • Dynamic: Burning Rock Biotech to use Myriad's myChoice homologous recombination deficiency (HRD) test in Phase III drug development studies and in clinics
Adaptive Biotechnologies	GlaxoSmithKline	• Objective: Use Adaptive's ClonoSeq assay to assess minimal residual disease (MRD) across GSK's portfolio of hematology products • Dynamic: GSK gets non-exclusive right to use ClonoSeq test in its hematology clinical trials to generate data supporting the clinical value of monitoring MRD for patient care • Adaptive to get upfront and potential future regulatory milestone payments
Genosity	Igentify	• Objective: Integrate Genosity's Integrated Genomic Toolkit into Igentify's genetic counseling software • Dynamic: Both firms to comarket the combined solution
SpeeDx	Nepean Hospital	• Objective: Commercialize host gene expression biomarker test for respiratory viral illness • Dynamic: Under exclusive deal, SpeeDx to work with Nepean scientists to develop an assay that uses IFI27 expression to support risk-based management of severe respiratory disease patients
Biocartis	GeneproDx	• Objective: Develop GeneproDx's ThyroidPrint on Biocartis' Idylla platform • Dynamic: GeneproDx to lead in developing the Idylla ThyroidPrint test, with Biocartis responsible for assay's global distribution

Partner 1	Partner(s) 2+	Deal Summary
Biocartis	Endpoint	• Objective: Develop and commercialize a novel companion diagnostic test on Biocartis' Idylla platform • Dynamic: Endpoint to lead development and registration of Idylla Endpoint CDx test in interventional trials, with both firms to collaborate on assay's commercialization
LabCorp	BML	• Objective: Expand availability of products developed by LabCorp's Covance drug development business in Japan, starting with oncology assays • Dynamic: Expands existing collaboration to broaden network of Japanese labs used to support companion diagnostic development and commercialization
Thermo Fisher Scientific	Terasaki Innovation Center	• Objective: Develop new diagnostic tools to manage transplant patients • Dynamic: Thermo Fisher to have first rights to new technologies developed by TIC for transplant medicine

DISTRIBUTION, SALES & MARKETING AGREEMENTS

Product Owner	Distributor	Deal Summary
CellaVision	Sysmex America	• Products: CellaVision's DC-1 product for automating blood cell differentials • Territory: US, Canada
Proteomics International Laboratories	Zotal	• Products: Proteomics' ELISA-based Promarker D (IA) diabetic kidney disease immunoassay • Territory: Israel • Exclusive
Take2 Health	Yourgene Health Taipei	• Products: Take2 Prophecy test • Territory: Taiwan
S2 Genomics	D-Mark Biosciences	• Products: S2's Singulator 100 system and associated products • Territory: Canada

Continued on page 20

DX Deals:, *from page 19*

LICENSES

Licensor	Licensee	Deal Summary
University of Southern California's Michelson Center for Convergent Bioscience	Epic Sciences	Epic gets access to Center's liquid biopsy samples to improve its liquid biopsy platform and gain more precise characterization of rare circulating tumor cells (CTCs)
TwinStrand Biosciences	Foundation Medicine	Foundation gets non-exclusive access to Twin Strand's duplex sequencing technology that independently tracks both strands of DNA molecules and compares paired sequences to eliminate errors
Qiagen	Phase Genomics	Qiagen non-exclusively licenses patents enabling it to sell its EpiTect Hi-C kits in US

SUPPLY, SERVICE & TESTING AGREEMENTS

Supplier/Servicer	Client/User	Deal Summary
Quest Diagnostics	Montefiore Nyack Hospital	Quest to provide Montefiore Nyack and its renal physician practice Highland Medical Rockland Renal Associates with lab management including day-to-day management of hospital labs, lab supply chain management and esoteric reference testing
Quest Diagnostics	Goshen Hospital	Quest to provide Goshen Hospital with supply chain management services
Quest Diagnostics	Nevada Department of Corrections	$10 million deal for Quest to provide COVID-19 testing at state prisons

M&A Report: Look for Health Care Mergers and Acquisitions to Resurge in 2021

Last year at this time, the expectation was that 2020 would be an unusually active year for health care mergers and acquisitions. But the pandemic forced deal makers to shelve their plans and await further developments. As the year comes to a close and the COVID-19 crisis comes to what may well prove to be its climax, talk of return to more active M&A deal making has returned.

Ripe Conditions for M&A Deals

In some ways, COVID-19 changed everything, and in other ways, it changed nothing, including the long-term financial factors that made the conditions ripe for M&A deals. Coming up with the capital to make a strategic acquisition will be less challenging in 2021. Liquidity is strong, thanks in part to CARES Act funding that enabled would-be acquirers to build up cash reserves. Low interest rates and the recovery of stock prices will also provide impetus for M&A deal making.

And even as equity value and liquidity burns a hole in the pockets of would-be acquirers, stress, uncertainty of survival and downward pressure on earnings in the health care markets, particularly to small and mid-sized labs and other providers, will also likely ensure a robust supply of acquisition targets. Genomics firms, hospital labs and freestanding test labs are among the candidates for acquisition. Outside the labs space, home healthcare and digital health technology companies that offer remote care management and better clinical outcomes at lower costs, will also generate strong interest.

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

MERGERS, ACQUISITIONS & ASSET SALES

Acquiring Company	Target(s)	Deal Summary
PerkinElmer	Horizon Discovery Group	• Price: $383 million cash • Status: Expected to close Q1 2021 • Acquisition of cell engineering firm enables PerkinElmer to add gene editing and gene modulation tools to its portfolio of automated life sciences discovery and applied genomics products
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

Continued on page 22

M&A Report, *from page 21*

Acquiring Company	Target(s)	Deal Summary
Calibre Scientific	Dianova	• Price: Undisclosed • Status: Closed • Calibre to integrate antibodies, immunoassays and molecular biology products into its Biozol Diagnostica to create distribution network for Germany, Austria and Switzerland
Intermountain Health	Sanford Health	• Price: Undisclosed • Status: Signed letter of intent to merge in 2021 • Merged entity to operate 70 hospitals and 435 clinics and provide senior care services in 366 locations in 24 states, with HQ in Sioux Falls, South Dakota
Prenetics	Oxsed	• Price: $13.1 million in cash • Status: Closed • Acquisition of University of Oxford spinout created to develop and launch Oxsed RaViD Direct rapid SARS-CoV-2 test
Eurofins VRL	Hawaii Cellular Therapy and Transplant Laboratory (HCTTL)	• Price: Undisclosed • Status: Closed Church's lab at Harvard • Acquisition deal expands Eurofins' US presence and strengthens Eurofins Transplant Diagnostics

HHS to FDA: Resume EUA Review of COVID-19 LDTs, And Do It Fast, *from page 1*

pandemic were LDTs created by testing companies, universities and medical centers, including molecular and antibody assays, as well as saliva and home-collection products. The demonstrated ability of labs to step up and meet the unprecedented demand for new COVID-19 tests seemed to vindicate the decades-old case for relaxing FDA regulation in the interest of innovation and public health.

The other impetus to rapid change was the current administration's general policy of cutting regulatory red tape for business. Historically protective of its regulatory authority over LDTs, the FDA needed a little prodding to loosen the reins. That prodding came on Aug.19 when the HHS announced that the FDA would no longer require premarket review for LDTs but that labs could still seek EUA voluntarily. In addition, the FDA would now have to use the notice and rulemaking process to create

new rules and could no longer regulate LDTs via website notices and other informal methods.

On Oct. 7, the FDA fired back by announcing that it was bowing out of EUA review for any LDTs to "make the best use" of its review resources and prioritize "innovative, high-throughput [tests] that have reduced reliance on supplies and been integral to expanding testing capacity." It was a head scratching decision to the extent that the COVID-19 tests that passed through the EUA pipeline were precisely the types of products the FDA's new policy purported to promote.

The decision, which applied not just to new submissions but also to LDT EUA applications already in the pipeline, threatened to chill LDT development by stripping labs of crucial liability protections. While supportive of the initial HHS policy, the lab industry criticized the FDA decision and called on the agency to continue to let labs continue to voluntarily seek EUA for COVID-19 LDTs.

HHS Orders FDA to Resume EUA Review

The most recent twist came on Nov. 16 when HHS Assistant Secretary for Health and White House coronavirus testing czar **Brett Giroir** ordered the FDA to resume EUA review of COVID-19 LDTs, and do it fast. The agency's orders are to clear the backlog of submissions created by its decision to cease review within 14 days. If, as is highly likely to prove the case, the FDA can't meet that deadline, the National Cancer Institute (NCI) will step in to help.

"We recognize the FDA has a huge workload," Giroir noted. "That's why we're trying to provide additional resources. I don't think anybody can question the scientific integrity of the NCI."

What's At Stake

The reason the HHS has chosen to intervene is the fear that labs won't create new LDTs for COVID-19 unless they can secure EUA because of potential liability exposure if the product doesn't work as planned. **Explanation:** Normally, new diagnostics and medical products must undergo long and extensive clinical review before they can reach the market. But in times of public health emergency, it becomes necessary to accelerate the standard review protocols. The upside of abbreviated vetting is that products become available faster; the downside is that they carry greater than normal risks to users. Accordingly, producers are at higher risk of being sued for products liability.

To ensure that fear of liability doesn't chill innovation, a federal law called the *Public Readiness and Emergency Preparedness Act* (PREP) provides immunity to test makers and other producers that create medical products in response to a public health emergency. The FDA decision not to perform EUA review of LDTs for COVID-19 effectively strips test makers of

Continued on page 24

HHS to FDA: Resume EUA Review of COVID-19 LDTs, And Do It Fast, *from page 23*

their PREP immunity and makes them a sitting duck for trial lawyers and products liability lawsuits.

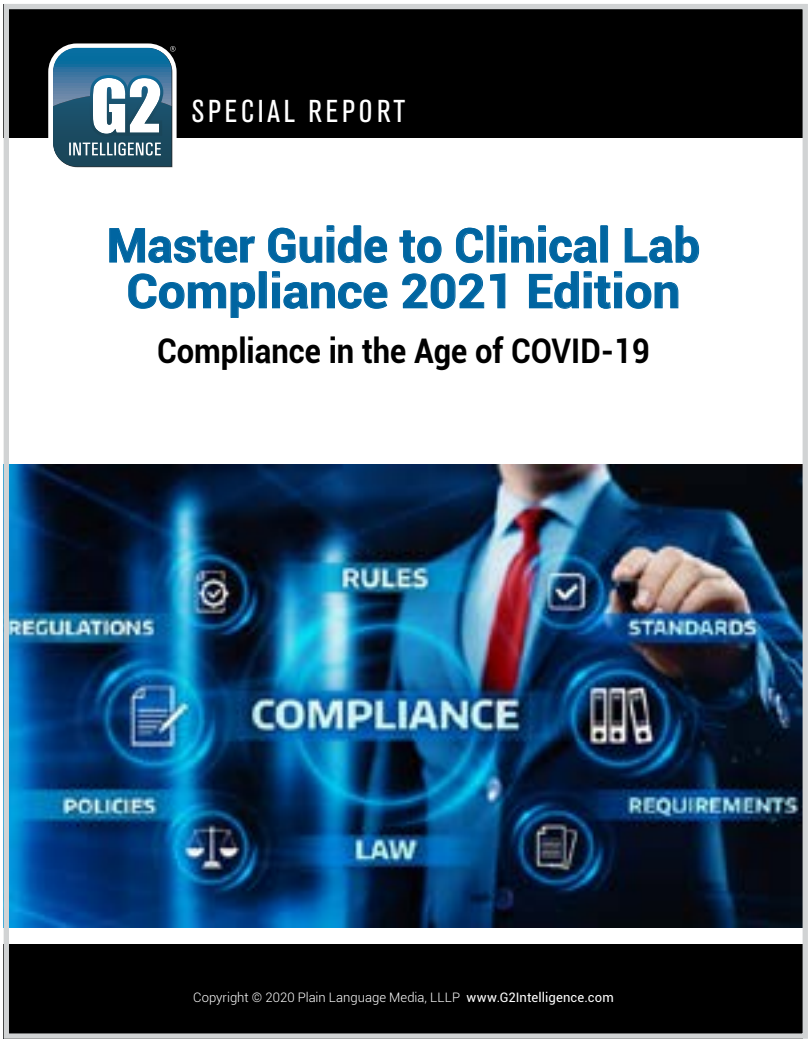
Giroir acknowledged that this was behind the order for FDA to resume EUA review of COVID-19 LDTs, noting on a media call that "without an EUA, although the tests can be used, they cannot receive liability protection under the PREP Act." Giroir added that the goal is to ensure that universities and other LDT makers are "given the same liability protection as major corporate developers and manufacturers."

Takeaway

Although not cited by HHS, there's another factor that makes the new policy so important and beneficial to makers of COVID-19 LDTs, namely, reimbursement. The Families First Coronavirus Response Act (FFCRA) requires commercial payors to cover medically necessary SARS-CoV-2 testing without cost sharing, but only if those tests have EUA from the FDA. Consequently, labs developing new SARS-CoV-2 LDTs without securing EUA status face the prospect of not being reimbursed for their tests.

Master Guide to Clinical Lab Compliance 2021

Compliance in the Age of COVID-19



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