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Inside the Lab Industry: Q3 Diagnostics Revenues Remain Strong Despite Fall in COVID-19 Testing

Lab companies posted another outstanding quarter of growth in Q3, with the recovery of core markets more than offsetting declines in COVID-19 tests and testing products. While lower on a sequential basis, growth was significant and widespread across a large number of companies, including those not in the COVID-19 space. Here's a rundown of the key earnings trends from Q3.

Top Line Growth

Of the 39 diagnostics firms (not counting foreign firms BioMérieux, DiaSorin, Roche and Siemens Healthineers)

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COVID Testing: Leading COVID-19 Test Makers Say Their Products Can Detect New Omicron Variant

The World Health Organization (WHO) has declared the new omicron (B.1.1.529) viral mutation a "variant of concern." But leading makers of COVID-19 diagnostic tests in the US seem unfazed and insist that they're prepared for the omicron challenge.

Do Current COVID-19 Tests Detect Omicron?

Omicron has now been reported in at least a dozen countries in Africa, Europe, the Eastern Mediterranean and Western Pacific regions, according to WHO. The last coronavirus variant to receive the WHO "variance of concern" label was

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that had reported their 2021 Q3 earnings as of press time, only three missed their top-line Wall Street earnings targets—Invitae, Nanostring Technologies and NeoGenomics, the latter of which just barely fell short. Nearly half of the companies (16) raised their revenues guidance for Q4 and the remainder of 2021, including heavyweights PerkinElmer, Quest, Roche and Thermo Fisher Scientific.

Continuing Q2 trends, most of the firms that reported positive top line growth in Q3 experienced growth at significantly reduced rates. Notable examples:

Sequential FY 2021 Quarterly Revenue Growth Rates

Company	Q3 Rate	Q2 Rate	Q1 Rate
Danaher	23 percent	34 percent	58 percent
Hologic	-2 percent	42 percent	104 percent
Lab Corp	4 percent	39 percent	52 percent
Opko Health	-10 percent	47 percent	>200 percent
PerkinElmer	21 percent	51 percent	100 percent
Qiagen	11 percent	28 percent	52 percent
Thermo Fisher Scientific	9 percent	34 percent	59 percent

While sequential growth is typically affected by seasonal issues, in 2021, it's also a reflection of year-over-year declines in COVID-19 demand. Thus, while COVID-19 products of all types flew off the shelves during Q3 of 2020, sales were far slower this year, with the exception of rapid, point-of-care products.

Bottom Line Disappoints

Another key earnings trend that continued was lower than expected net profits and wider than expected net losses. For the second straight quarter, 12 companies missed their bottom line Wall Street targets in Q3, as compared to just eight in Q1. Companies with disappointing earnings per share included:

Companies that Missed on Q3 Net Earnings

Company	Wall Street Target EPS	Actual Q3 EPS
Cue Health (Net)	+$1.48	+$0.14
Exact Sciences (Net)	-$0.85	-$0.95
Guardant Health (Net)	-$0.96	-$1.06
Invitae (Non GAAP)	-$0.71	-$0.81
Natera (Net)	-$1.27	-$1.63
Twist Bioscience (Net)	-$0.74	-$0.84

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However, the bottom line losses were mostly absorbed by smaller, less mature companies; all 10 testing firms that reported 9-figure revenues easily met and exceeded their Q3 EPS targets, including Abbott, Agilent Technologies, Becton Dickinson, Danaher, Hologic, Lab Corp, PerkinElmer, Quest and Thermo Fisher Scientific.

Core Markets Creep Back to Near Pre-Pandemic Levels

One of the positive trends of Q3 was the continued recovery of core products. While genomics, immunoassays, cancer, reproductive health and other non-COVID-19 businesses have been slowly inching up since FY 2020 Q4, the turnaround became widespread in Q2. This upward trajectory not only kept but increased momentum in Q3, with companies inside and outside the COVID-19 testing market reporting strong, albeit not quite pre-pandemic level, growth in core testing, life sciences and instrumentation products and services.

The Uncertain Future

While almost all companies have felt comfortable enough to issue guidance for the coming Q4 and full 2021 year revenues, the future beyond December remains uncertain. Even before reports of the new omicron SARS-CoV-2 variant began to appear, there were new, disturbing signs of a winter surge of flu-demic pairing COVID-19 with seasonal influenza. While that would go a long way toward restoring COVID-19 revenues, it could wreak devastation on base sectors just beginning to get their pre-pandemic legs back. Meanwhile, labs face the perennial reimbursement challenges, including ever deeper PAMA Part B Medicare cuts and growing resistance from private payors.

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Diagnostics Earning Reports for 2021 Q3 (period ended September 30, 2021)
(Companies with at least $20 million in sales)

COMPANY	FY 2021 Q3			DX Segment Performance
	Total Revenue (vs. Wall Street)	YOY Revenues	EPS (vs. Wall Street)	
Abbott Laboratories	$10.93 billion ($9.56 billion)	+24% (+22% organic)	Adjusted +$1.40 (+$0.94)	DX up 48% to $3.91 billion. Core DX up 9% to $1.29 billion as base business continues to recover; Molecular down again, this time 25% to $345 million; Rapid diagnostics up 145% to $2.14 billion; After Q2 dip, point of care up 3% to $135 million; COVID testing revenues of $1.9 billion (vs. $881 million in Q3 2020)

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COMPANY	FY 2021 Q3 Total Revenue (vs. Wall Street)	FY 2021 Q3 YOY Revenues	FY 2021 Q3 EPS (vs. Wall Street)	DX Segment Performance
Adaptive Biotech	$39.5 million ($36.6 million)	+50%	Net -$.27 (-$.42)	Sequencing revenues continue rebound nearly doubling to $22.1 million, with test volume for ClonoSeq up 47%; Development revenues up 16% to $17.4 million driven by higher demand for biopharma services
Agilent Technologies (FY 2021 Q4)	$1.66 billion ($1.47 billion)	+12%	Adjusted +$1.21 (+$1.04)	Genomics up 16% (vs 44% in Q3) to $341 million; Life sciences and applied market groups up 11% (vs 22% in Q3) to $747 million; Agilent Cross Lab up 10% to $572 million
Becton Dickinson (FY 2021 Q4)	$5.14 billion ($4.91 billion)	+7% (vs. 27% in Q3)	Adjusted +$2.59 (+$2.46)	Recovery in demand for specimen management products and microbiology solutions drives life sciences up 3% to $1.53 billion, despite modest decline in integrated DX solutions, with Biosciences up 16% to $352 million; BD Max up 20% to $110 million
Berkeley Lights	$24.3 million ($23.1 million)	+34% (vs. 82% in Q2)	Net -$0.30 (-$0.24)	Product revenues up 18% to $16.7 million; Service revenues jump 86% to $7.6 million; Direct platform revenues, including instruments, license agreements and platform support, up 14% to $14.1 million
*BioMérieux	$1.02 billion	+11% (+12% organic)		Clinical applications up 11% to €756.6 million, including 14% increase in microbiology to €269.8 million, driven by reagent sales, 6% increase in molecular biology to €338 million, driven by 19% uptick in BioFire reagent sales and growth of BioFire Film Array installed base (now at 21,400 systems); Immunoassays up 8% to €120.3 million
Bio-Techne (2022 Q1)	$257.7 million ($252.4 million)	+26% (vs. 47% in Q4)	Adjusted +$1.83 (+$1.72)	DX & Genomics up 22% to $61.0 million; Protein Sciences up 28% to $197.2 million; Broad growth in proteomic research reagents and analytical tools
***Bruker**	$608.9 million ($575.2 million)	+19% (vs. 34% in Q2)	Adjusted +$0.63 (+$0.44)	CALID group, which houses life science mass spectrometry, up 13% to $194.2 million driven by strong demand for high-performance instruments and sales of timsTOF mass spec and MALDI-TOF platforms; Molecular COVID testing continues decline with $5 million in sales
***CareDx**	$75.6 million ($74.1 million)	+42% (vs. 77% in Q2)	Adjusted +$0.07 (+$0.01)	After nearly doubling in Q2, testing services up 46% to $66.5 million with testing volumes up 86%, including 40,000 AlloSure blood and AlloMapHeart transplant tests returned; Product revenues up 20% to $6.5 million
Castle Biosciences	$23.5 million ($23.0 million)	+54%	Net -$0.47 (-$0.40)	Top line growth driven by 62% increase in gene expression profile tests delivered to 7,727 and comes despite -$100,000 in reverse accounting adjustments

COMPANY	FY 2021 Q3 Total Revenue (vs. Wall Street)	FY 2021 Q3 YOY Revenues	FY 2021 Q3 EPS (vs. Wall Street)	DX Segment Performance
Cue Health	$223.7 million ($200.3 million)	Over hundred-fold	Net +$0.13 (+$1.48)	Product revenues go from $2.1 million to $222.6 million, driven by 74% sequential quarterly growth in disposable test cartridges to $179.0 million
Danaher	$7.23 billion ($7.00 billion)	+23%	Adjusted +$2.39 (+$2.15)	Life sciences continues to drive growth, increasing 25% to $3.73 billion; Diagnostics up from $1.89 to $2.45 billion, including 60% growth in Cepheid unit—16 million respiratory cartridges shipped, 80% for COVID only test and 20% for SARS-CoV-2 4-in-1 test
DiaSorin	€343.5 million ($393.9 million)	+51%		Strong recovery in non-COVID revenues, which grew 8.4%, excluding newly acquired Luminex; CLIA test revenues up 23% to €140.4 million; ELISA test revenues down 11% to €14.5 million; Molecular up 6% to €82.1 million; Instruments down 21% to €15.4 million
***Exact Sciences**	$456.4 million ($430.0 million)	+12% (vs. 62% in Q2)	Net -$0.97 (-$0.85)	Screening revenues up 31% to $280.4 million, despite weaker than expected growth in Cologuard due to rise in Delta variant; Precision oncology, including Oncotype products continue strong rebound, up 59% to $145.4 million, while COVID testing continues decline with 70% drop to $30.6 million
Guardant Health	$94.8 million ($92.6 million)	+27% (vs. 39% in Q2)	Net -$1.06 (-$0.96)	Precision oncology up 31% to $79.3 million driven by 27% increase in clinical testing; Development services up 9% to $15.5 million; Overall test volume up 35% to 22,806 total tests
Hologic (FY 2021 Q4)	$1.32 billion ($1.04 billion)	-2% (vs. +42% in Q3)	Adjusted +$1.61 (+$1.01)	Product revenues down 5% to $1.14 billion; Services up 24% to $178.7 million; Total DX, excluding divested blood screening, down 12% (vs. +25% in Q3 and +233% in Q2) to $820.5 million, with 14% decline in molecular diagnostics to $704.5 million, 4% increase in cytology and perinatal to $116.0 million; Outside DX, Breast Health up 16% to $334.2 million and Gyn surgical up 22% to $122.0 million; 167 Panther molecular DX instruments placed in quarter
***Illumina**	$1.11 billion ($1.05 billion)	+40% (vs. +78% in Q2)	Net +$1.45 +$1.14	Core Illumina accounts for almost all revenues with newly acquired Grail contributing $2 million; Product revenues of $978 million and Other revenues of $130 million
**Invitae	$114.4 million ($126.6 million)	+66% (vs. +152% in Q2)	Non GAAP -$0.81 (-$0.71)	Testing up 66% to $111.7 million driven by 89% increase in billable test volume (296,000 tests billed); Other revenues nearly double to $2.7 million; Oncology up 64% to $69 million; Women's health up nearly doubles to $21 million

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COMPANY	FY 2021 Q3 Total Revenue (vs. Wall Street)	FY 2021 Q3 YOY Revenues	FY 2021 Q3 EPS (vs. Wall Street)	DX Segment Performance
***LabCorp**	$4.06 billion ($3.65 billion)	+4% (vs. 39% in Q2)	Adjusted +$6.82 (+$4.92)	DX goes from 40% growth in Q2 to 3% decline in Q3 ($2.62 billion), as 6% increase in base testing offset by 10% decline in COVID testing; 85,000 SARS-CoV-2 tests per day, vs. 54,000 per day in Q2; Covance up 18% to $1.46 billion, vs. 37% growth in Q2
Myriad Genetics	$167.3 million ($165.0 million)	+15%	Adjusted -$0.02 (-$0.02)	Molecular DX up 23% (vs. 115% increase in last quarter) to $167.3 million); Hereditary cancer back down 1% after 2Q 116% growth, to $79.4 million; Prenatal up 42% to $23.6 million; Tumor profiling up 94% to $32.9 million driven by Prolaris and myChoiceCDx; Mental health, including GeneSight test, more than doubles to $24.1 million
**Nanostring Technologies	$37.2 million ($37.8 million)	+17% (vs. +50% in Q2)		Instruments up 13% to $14.5 million, including 14% growth in GeoMx Digital Spatial Profiler and 11% growth in nCounter Analysis System sales; Consumables up over 32%; Services up 22% to $4.4 million
***Natera**	$158.1 million ($151.4 million)	+61%	Net -$1.63 (-$1.27)	Product revenues up 62% to $150.7 million, driven by 55% increase in test volumes (407,300 tests), with strength in women's health, oncology and transplant
**NeoGenomics	$121.3 million ($125.1 million)	-3% (vs. +40% in Q2)	Adjusted -$0.08 (-$0.09)	Excluding 2020 Q3 COVID revenues, revenue would have increased 12%; Clinical services down 6% to $102.2 million; average revenue per test up 4% to $375; Pharma services up 14% to $2.4 million
Opko Health	$385.8 million ($302.3 million)	-10% (vs. 47% increase in Q2)	Pro forma +$0.04 (-$0.01)	Fall off in COVID testing drives 11% drop in DX Services to $340.1 million; Losses partially offset by 125% increase in genomics testing and greater recoveries of COVID reimbursements; Hematology and NGS drive 20% growth in oncology; Product revenues up 29% to $28.7 million
***OraSure Technologies**	$53.9 million ($47.5 million)	+12% (vs. up 97% in Q2)	Net -$0.02 (+$0.04)	Excluding 2020 Q3 COVID revenues, revenue would have grown 37%; Molecular down 4% to $30.3 million, despite 125% growth in genomics collection kits to $19.0 million; Sample collection devices for COVID testing down 67% to $6.3 million; OraSure and OraQuick tests for HIV and Hepatitis C down 2% to $12.7 million
Pacific Biosciences	$34.9 million ($33.2 million)	+83%	Net -$0.23 (-$0.22)	Third straight quarter of solid growth; Product revenues nearly double to $30.5 million, including $15.9 million in Instruments and $14.6 million in Consumables (up 82%); 44 Sequel II and IIe systems placed, nearly doubling total instruments placed to 326

COMPANY	FY 2021 Q3 Total Revenue (vs. Wall Street)	FY 2021 Q3 YOY Revenues	FY 2021 Q3 EPS (vs. Wall Street)	DX Segment Performance
***PerkinElmer**	$1.17 billion ($1.04 billion)	+21% (vs. +51% in Q2)	Adjusted +$2.31 (+$1.73)	DX revenues of $654 million vs. $540 million in Q3 2020; Discovery and Analytical Solutions with $513 million vs. $424 million; Non-COVID organic revenues up 16% vs. 12% expected; Within DX, immunodiagnostics up over 40%, with Euroimmun up 20% organically
***Personalis**	$22.3 million ($22.2 million)	+12%	Net -$0.40 (-$0.42)	Revenues from VA sequencing services government contract down 3% to $13.7 million but revenues from other clients up 51% to record-high of $8.6 million
***Qiagen**	$534.7 million ($435.6 million)	+11% (vs. 28% in Q2)	Adjusted +$0.58 (+$0.47)	Non-COVID revenues up 17% to $376 million, while COVID products continue decline, dipping 4% to $159 million; Consumables up 13% to $473 million; Instruments down 3% to $62 million; Molecular up 18% to $279 million; PCR/ nucleic acid amplification up 3% to $98 million
Quanterix	$27.7 million ($24.0 million)	-12%	Adjusted Not given (-$0.36)	Product revenues up 77% to $20.7 million but Services and Other Revenues fall 10% to $5.9 million
***Quest Diagnostics**	$2.77 billion ($2.45 billion)	-1% (vs. + 40% in Q2)	Adjusted +$3.96 (+$2.87)	Flat revenues result of sharp decline in COVID testing, as compared to Q3 2020; however, Base testing continues to recover, with volumes up 9% (4% excluding acquisitions) and exceeds 2019 levels for first time since pandemic began, and growth is robust as compared to 2019; Total requisitions up 5%, but revenues per requisition down 5%
Quidel	$509.7 million ($376.8 million)	+7%	Adjusted +$5.36 (+$3.52)	Growth driven by COVID DX tests led by Quick Vue At-Home OTC; Core businesses excluding COVID up 2% to $93.3 million; Molecular DX down 13% to $54.8 million due to $14.3 decline in Lyra PCR assays for COVID, partially offset by incremental revenues from Solana SARS-CoV-2 assay
*Roche Diagnostics	CHF 4.26 billion ($4.65 billion)	+18%		For first 9 months of 2021, DX up 38% to CHF 13.31 billion, with CHF 3.5 billion in COVID sales; Core lab revenues up 26% to CHF 5.61 billion driven by immunodiagnostics, especially infectious diseases and cardiology tests; Molecular DX up 36% to $3.45 billion driven by COVID PCR testing; Pathology lab up 14% to CHF 889 million
Sema4	$43.2 million ($42.7 million)	+12%	Net +$0.15 (+$0.15)	Excluding COVID, revenues up 17%; DX up 9% to $41.4 million, although COVID tests decline 21% to $4.2 million; Just under 70,000 tests processed, not counting COVID
Siemens Healthineers (FY 2021, Q4)	€5.16 billion	+33%	Adjusted +€0.53	DX up 23% to €1.28 billion, driven by €160 million in rapid SARS-CoV-2 antigen tests; DX up 7%, excluding COVID tests; Continued recovery in core non-COVID businesses

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Inside the Lab Industry: Q3 Diagnostics Revenues Remain Strong Despite Fall in COVID-19 Testing, *from page 7*

COMPANY	FY 2021 Q3 Total Revenue (vs. Wall Street)	FY 2021 Q3 YOY Revenues	FY 2021 Q3 EPS (vs. Wall Street)	DX Segment Performance
***Thermo Fisher Scientific**	$9.33 billion ($8.39 billion)	+9% (vs. 34% in Q2 and 59% in Q1)	Adjusted +$5.76 (+$4.67)	Life sciences up 9% (vs. 137% in Q1 and 37% in Q2) to $3.72 billion; Specialty DX goes from 25% increase in Q2 and 69% in Q1 to 5% decline in Q3 to $1.36 billion; Analytical instruments up 11% (vs. 26% in Q2) to $1.48 billion; Laboratory products and services revenues up 12% (vs. 29% in Q2) to $3.11 billion
***10x Genomics**	$125.3 million ($122.6 million)	+74%	Net -$0.15 (-$0.20)	Consumables up 75% to $106.1 million, thanks to growth in numbers of instruments installed; Instruments up 77% to $17.1 million, driven by launch of Chromium X; Services up 30% to $2.1 million
Twist Bioscience (FY 2021, Q4)	$38.0 million ($37.0 million)	+17%	Net -$0.84 (-$0.74)	Next-generation sequencing revenues, including SNP microarray conversions and liquid biopsy panels of $21.4 million, topping Synthetic biology revenues ($13 million) for fourth quarter in a row; Biopharma revenues of $2.6 million
***Veracyte**	$60.4 million ($54.4 million)	+94%	Net -$0.20 (-$0.16)	Overall testing revenues of $53.9 million with testing 79% growth in Affirma, Percepta and Envisia (just under 21,000 tests); Product revenues of $6.5 million
Waters	$659.2 million ($656.5 million)	+11%	Non-GAAP +$2.66 (+$2.35)	After 2 straight quarters of 31% growth, revenues continue up; Growth driven by double-digit spike in instruments and recurring revenues; Sales up in pharma market 16% and in industrial market 9%

Bold face: Companies that met or exceeded average or consensus Q2 Wall Street revenue estimates

* Companies that raised their revenue or EPS guidance during Q2

** Companies that lowered their revenue or EPS guidance during Q2

DX Deals: New Saliva-Based Pregnancy Test May Revolutionize POC Diagnostics

The global pandemic has forced test makers to accelerate development of innovative rapid, point-of-care diagnostics. While COVID-19 detection remains the paramount objective, pandemic pressures may also lead to breakthroughs in other areas. One potential game changer could end up revolutionizing the kind of home test women who miss a period use to determine if they're pregnant. Using COVID-19 detection technology to fertilize an idea gestated before the pandemic, Israeli medical start-up

Salignostics is getting ready to launch the world's first pregnancy test based on saliva samples.

The Untapped Potential of Saliva-Based Pregnancy Diagnostics

In addition to being easy to detect and store, saliva contains biomarkers that can be used for early detection of different diseases and medical conditions. The presence of multiple biomarkers makes saliva ideal for development of simple, noninvasive multiplexed assays that can be performed quickly at the point of care. One of the most promising of these biomarkers is beta-human chorionic gonadotropin (β-hCG), measurement of which can be used to detect levels of hormones associated with pregnancy. β-hCG levels in saliva are usually detectable at about three to four weeks into pregnancy and continue to increase as the pregnancy continues.

But despite its potential diagnostic advantages, there have been only a few studies evaluating the role of saliva and β-hCG as a noninvasive, rapid, and more acceptable biofluid for pregnancy detection. One study supporting the viability of using β-hCG levels in saliva to detect pregnancy was published in the journal *Gynecology and Minimally Invasive Therapy* in June 2019.

The New Saliva-Based Pregnancy Test

Perhaps encouraged by the GMIT study, Jerusalem-based Salignostics set out to use its proprietary saliva-based hormone detection technology to develop a home test for early pregnancy detection. Like so many other companies did when the pandemic arrived, Salignostics shelved its plans to concentrate on COVID-19 testing. But something unexpected happened along the way. In developing its SaliCov rapid antigen test for COVID-19, which has received CE Marking from the European Union (EU) and is now widely used across Europe and Africa, Salignostics uncovered the missing piece they needed to bring the pregnancy assay to fruition.

The company reports that its resulting SaliStick test product has 95 percent sensitivity when women use it after they have missed a period. The company has successfully completed clinical trials in Israel on more than 300 women—both pregnant and non-pregnant—and has begun the process of applying for CE Marking and US Food and Drug Administration (FDA) approval. If it all works out, the company plans call for a commercial launch early in 2022.

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Dx Deals, *from page 9*

Here's a summary of some of the key strategic diagnostic deals announced in November 2021:

STRATEGIC ALLIANCES, PARTNERSHIPS & COLLABORATIONS

Partner 1	Partner(s) 2+	Deal Summary
Exact Sciences	Jefferson Health hospital	• Objective: Perform research on Exact's new blood-based, multicancer earlier detection (MCED) test • Dynamic: Survey Jefferson health system doctors and patients to evaluate MCED test's safety and efficacy and facilitate effective MCED testing
Roche	I-Mab	• Objective: Jointly develop companion diagnostics for China-based I-Mab's biologics products and accelerate R&D process • Dynamic: New collaboration building on previous agreement between Ventana and I-Mab, with initial focus being development of a companion diagnostic test for a solid tumor-associated antibody by immunohistochemistry
Burning Rock Biotech	Merck	• Objective: Develop companion diagnostic for MET inhibitor tepotinib (Tepmetko) in mainland China market • Dynamic: Leverage Burning Rock's OncoCompass Target blood-based next-generation sequencing assay targeting 168 biomarkers, including MET
Burning Rock Biotech	Impact Therapeutics	• Objective: Furnish testing services to support Impact Therapeutics' development of ATR inhibitor IMP9064 in China and US • Dynamic: Pharma firm's most recent collaboration with Chinese genomics firms with Burning Rock to perform genetic testing of trial participants in its Guangzhou and California labs
Helix	Cue Health	• Objective: Generate SARS-CoV-2 sequencing data for study of individuals who test positive for virus with Cue Health's at-home COVID-19 test • Dynamic: Positive subjects can opt into virus variant sequencing study by providing specimens for analysis with Helix research-use-only variant sequencing test with test results provided via the Cue Health App

Partner 1	Partner(s) 2+	Deal Summary
Cellenion	Bruker	• Objective: Comarket tools for single-cell proteomics experiments • Dynamic: Market Cellenion's CellenOne single-cell isolation and dispensing system with Bruker's timsTOF SCP mass spectrometer to enable label-free single-cell proteomics workflows
Cellenion	Thermo Fisher Scientific	• Objective: Develop workflows for single-cell, mass spectrometry-based proteomics analyses • Dynamic: Comarketing agreement to combine combine Cellenion's CellenOne single-cell isolation system and ProteoChip consumable with Thermo Fisher's TMT multiplexing technologies and Orbitrap mass spectrometers
Lucence	VA Palo Alto Health Care System	• Objective: Launch observational study to evaluate use of sequencing-based LiquidHallmark liquid biopsy assay in a screening context • Dynamic: Study to compare study will compare the sensitivity and specificity of positron emission tomography-computed tomography (PET/CT), alone versus PET/CT in combination with LiquidHallmark in detecting lung cancer nodules between 6 and 20 millimeters
Genomenon	Inozyme Pharma	• Objective: Improve diagnosis and treatment of ENPP1 deficiency, aka, generalized arterial calcification of infancy or autosomal recessive hypophosphatemic rickets Type 2 • Dynamic: Provide molecular diagnostic data on a rare pediatric-onset calcification disorder to testing labs and clinicians
Genomenon	Deep 6 AI	• Objective: Research cancer, Parkinson's, Wilson's disease and other diseases • Dynamic: Proof-of-concept agreement to explore integrating Deep 6 AI's software for mining patient records, and genomics and pathology data to support trial-feasibility site selection and patient recruitment with Genomenon's AI-powered Genomic Landscapes platform for matching patients to trial inclusion criteria
Genetron Health	NeoGenomics	• Objective: Support NeoGenomics' drug development clinical trials • Dynamic: Use respective technology platforms and product pipelines to help business partners synchronize global clinical drug trials and companion diagnostics development

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Dx Deals, *from page 11*

Partner 1	Partner(s) 2+	Deal Summary
Scipher Medicine	GNS Healthcare	• Objective: Develop and launch Gemini, the in silico Patient, for rheumatoid arthritis • Dynamic: Patient model to use Scipher's clinic-genomic patient data in RA generated from firm's PrismRA liquid signature blood test to predict non-response to TNFi therapies in rheumatoid arthritis patients
Scipher Medicine	Tara Biosystems	• Objective: Identify therapeutic targets for drug development in cardiac laminopathies • Dynamic: Scipher to use its Spectra platform to identify potentially therapeutic targets from proteins up- and downstream of LMNA for a stratified disease population, while incorporating data from Tara's Biowire II LMNA disease models
Saga Diagnostics	AstraZeneca	• Objective: Develop digital PCR assays for undisclosed methylated targets in tissue and liquid biopsies • Dynamic: Leverage Saga's SagaSafe (formerly IBSafe) digital PCR method for improving sensitivity
Deep Bio	Morphle Labs	• Objective: Give pathologists access to AI-based prostate-specific tissue image analysis and Morphle Labs' remote microscopy workflow scanner • Dynamic: Integrate Deep Bio's DeepDx Prostate software with Morphle Labs' slide scanners
Sciex	Evosep	• Objective: Comarket Sciex's mass spectrometry with Evosep's liquid chromatography systems for high-throughput proteomics workflows • Dynamic: Sciex to market its ZenoTOF 7600 mass spec system with Denmark-based Evosep's Evosep One LC system
SomaLogic	University Hospitals Cleveland Medical Center	• Objective: Evaluate the impact of SomaLogic's SomaSignal tests on managing diabetic patients at high risk of cardiovascular disease • Dynamic: Use test in clinical trials for identifying diabetic patients with elevated risk for cardiovascular disease and tracking effectiveness of therapies such as SGLT-2 inhibitors and GLP-1 agonists on those patients
Numares	Oxford University Innovation	• Objective: Develop multimarker test to detect multiple sclerosis disease progression • Dynamic: Exclusive license with Numares to develop MS biomarkers that identified by Oxford University into an in vitro diagnostic test

DISTRIBUTION, SALES & MARKETING AGREEMENTS

Product Owner	Distributor	Deal Summary
PathogenDx	Axiology Labs	• Products: PathogenDx's Detectx-Cv SARS-CoV-2 variant assay technology • Territory: Africa (12 countries), Thailand
Mission Bio	Alliance Global	• Products: Mission Bio's single-cell sequencing Tapestri platform and other products • Territory: Middle East, Africa • Exclusive
Mission Bio	Bioké	• Products: Mission Bio's single-cell sequencing Tapestri platform • Territory: Belgium, Netherlands, Luxembourg
PerkinElmer	GenWorks Health	• Products: PE's newborn and prenatal screening products • Territory: India • Exclusive

LICENSES

Licensor	Licensee	Deal Summary
Spanish National Research Council (CSIC)	World Health Organization and the Medicines Patent Pool (MPP)	MPP licenses CSIC's rapid manufacture and commercialization of COVID-19 antibody testing technology
University of Maryland, Baltimore + University of Maryland, Baltimore County	RNA Disease Diagnostics	RNA Disease Diagnostics licenses RNA-based lateral flow assay technology that for use to develop at-home molecular SARS-CoV-2 and influenza test kits

GOVERNMENT CONTRACTS

Contractor	Govt. Agency	Contract Summary
Quest	Texas Department of State Health Services	Quest to provide COVID-19 testing for K-12 schools in Texas via its labs in the Houston and Dallas-Fort Worth areas
Eurofins Genomics US	US Department of the Air Force and Department of Health and Human Services	$30 million contract to build a new production facility and to expand manufacturing capacity for reagents used in COVID-19 diagnostic tests
OraSure Technologies	US Department of Defense	$109 million contract for manufacturing scale-up for OraSure's InteliSwab rapid SARS-CoV-2 antigen assays

FDA WATCH

HHS Restores Agency's Premarket Review of LDTs

For over a year, makers of laboratory developed tests (LDTs) have been free of the yoke of US Food and Drug Administration (FDA) premarket review requirements. But on November, the Department of Health and Human Services (HHS) restored order by announcing that the agency will resume premarket review and emergency use authorization (EUA) of new lab tests. Adding to the effect, HHS has also imposed new limitations on which COVID-19 tests will be allowed to reach the market via the EUA pathway. Here's a rundown of the latest twist in the story of FDA regulation of LDTs during the public health emergency.

How FDA Regulates LDTs

The COVID-19 public health emergency laid bare a truth that the lab industry has been pointing out for decades: the FDA's makeshift and improvised regulation of LDTs via the premarket pathway is ineffective and blocks badly needed innovative tests from reaching the market. Put into the context of a global pandemic, the need to address this perennial problem assumed a new urgency.

The FDA responded in March 2020 by unveiling a new policy allowing labs to develop and utilize their own tests, provided that they notify the agency that they were shipping products. In May, when it had become clear that the new policy had gone too far in the other direction by allowing unproven tests of dubious value to reach the market, the FDA changed course by requiring EUA for diagnostic tests.

In August 2020, HHS took matters into its own hands by ordering FDA not to require premarket review for LDTs. This latest surprise policy reversal was heavily criticized as another overreaction, one that threatened to undermine the agency's ability to provide critical advice to test developers and crack down on bad tests.

New Policy Restores Premarket Review of LDTs

With supplies of COVID-19 tests stabilizing and high-profile Class I recalls threatening public confidence in test reliability, HHS has made still another 180⁰ turn by retracting the August 2020 policy of allowing makers of LDTs to bypass the 510(k) premarket review clearance and EUA processes. From now on, LDTs will once more be subject to the historic review rules and won't receive separate treatment.

Consequences: Test makers currently offering tests launched without submission of an EUA request will have to submit an EUA request. In addition, the agency will review pending EUA request submissions for LDTs. If the agency doesn't subsequently approve the EUA request, it will notify the test maker who will then have to stop marketing the product within 15 calendar days.

New Limits on Access to EUA Process

But the November 15 new/old policy does more than simply restore the pre-August status quo; it also sets new limits on which SARS-CoV-2 tests will be able to use the EUA pathway. Specifically, FDA will now concentrate on high throughput tests that can be manufactured in large volumes, including at-home and POC tests for use on a prescription and OTC basis. Also receiving priority will be SARS-CoV-2 assays and diagnostics that offer the potential to expand testing capacity, including:

- Tests that can be performed on using specimen pooling methods;
- High-volume, laboratory-based molecular diagnostic tests in which specimens are collected at home and shipped to a laboratory;
- Tests designed for screening asymptomatic populations; and
- Multianalyte and other tests that are capable of detecting multiple different types of respiratory viruses at once.

Access to the EUA pathway will also remain open to laboratory-based and POC high-volume antibody tests that measure the amount of antibodies in a patient's system, such as fully quantitative antibody tests that measure neutralizing antibodies.

Finally, FDA will also afford priority to tests for which request for EUA clearance comes from a US government entity, such as the Biomedical Advanced Research and Development Authority (BARDA) or the US National Institutes of Health's Rapid Acceleration of Diagnostics (RADx) initiative.

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Here are some of the key new FDA EUAs and clearances announced in November 2021:

New FDA Emergency Use Authorizations (EUAs) & Approvals (NEW)

Manufacturer(s)	Product
InBios International	EUA for SCoV-2 Ag Detect Rapid Self-Test, over-the-counter SARS-CoV-2 home antigen test
Meridian Bioscience	EUA for Revogene SARS-CoV-2 molecular test run on firm's Revogene instrument
Talis Biomedical	EUA for Talis One COVID-19 point-of-care test
iHealth	EUA for COVID-19 Antigen Rapid Test lateral flow assay
LumiraDx	Expanded EUA for use of COVID-19 antigen test to test the asymptomatic
BloodHub	510(k) clearance for version v1.1.0 of BloodRelay blood establishment inventory management software

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Manufacturer(s)	Product
Clever Culture Systems	510(k) clearance for APAS Independence platform for bacterial culture analysis for use with methicillin-resistant *Staphylococcus aureus* samples
Detect	EUA for over-the-counter, at-home Detect SARS-CoV-2 Test
Ortho Clinical Diagnostics	510(k) clearance for Vitros Immunodiagnostic Products NT-proBNP II Reagent Pack to measure N-terminal pro brain natriuretic peptide
Siemens Healthineers	510(k) clearance for N Latex FLC Kappa and Lambda IVD reagents to detect kappa and lambda free light chains in serum
Roche	510(k) clearance for Cobas Cdiff real-time PCR nucleic acid test run on firm's Cobas Liat point-of-care system

New CE Marks & Global Certifications

Notable European CE certifications announced during the period:

NEW CE MARKINGS IN EUROPE

Manufacturer(s)	Product(s)
NGeneBio	HLAaccuTest, NGS-based human leukocyte antigen (HLA) typing assay
DiaSorin + MeMed	Liaison MeMed BV high-throughput, immune-response assay
Roche	New Cobas 5800 molecular instrument
BforCure	Bfast SARS-CoV-2 RT-PCT kit
Genetron Health	Onco PanScan genomic profiling test for cancer
Qiagen	QiaStat-Dx Respiratory 4 Plex Flu A-B/RSV/SARS-CoV-2 test to distinguish seasonal respiratory infection from SARS-CoV-2
Scope Fluidics	BacterOmic system to diagnose the antimicrobial susceptibility of bacteria causing respiratory, blood, urinary tract and skin infections
Agilent Technologies	Expanded use of PD-L1 IHC 22C3 pharmDx CDx to identify patients with triple-negative breast cancer

Other international clearances announced during the period:

Manufacturer(s)	Country(ies)	Product(s)
Co-Diagnostics	England	Logix Smart SARS-CoV-2 DS test
Berry Genomics	China	Version of Sequel II instrument

COVID Testing: Leading COVID-19 Test Makers Say Their Products Can Detect New Omicron Variant, *from page 1*

the delta variant, which currently accounts for virtually all COVID-19 cases in the US.

One of the reasons the COVID-19 pandemic was so devastating is that the virus was an unknown entity for which lab tests hadn't been designed. Now that the new omicron variant has emerged, there are widespread fears that we may be right back where we started. The encouraging news is that current COVID-19 tests have proven effective in detecting the delta variant.

COVID-19 Test Makers Say They're Ready for Omicron

While omicron has yet to reach American soil, several of the nation's leading makers of COVID-19 tests have expressed confidence that their products will prove capable of detecting the new variant.

On November 27, Abbott Laboratories issued a statement indicating that it's monitoring the situation and is "confident" that its polymerase chain reaction (PCR) and rapid antigen tests can detect omicron, noting that those tests don't rely on the spike gene to detect the virus. "We are actively collecting real-world samples and using viral cultures to verify that our tests continually detect circulating strains because we know how important it is that our tests can detect new variants regardless of where they are found," the Abbott statement notes.

Two days later, Hologic stated that it has determined via analysis of genetic sequences that all three of its COVID-19 tests—the Aptima SARS-CoV-2 Assay, Aptima SARS-CoV-2/Flu Assay and Panther Fusion SARS-CoV-2 Assay—detect the new omicron variant. Other test makers that have issued statements of reassurance include:

- Thermo Fisher Scientific, which said that its two PCR TaqPath kits aren't impacted by omicron;
- Qiagen, which announced that its PCR tests remain accurate and effective in detecting SARS-CoV-2 infections, including those caused by the omicron variant;
- Lucira Health, which stated that its assessment confirms the capability of the firm's COVID-19 Check-It (OTC) and All-In-One (Rx) molecular self-test kits "to detect 100% of Omicron variant genome sequences analyzed";
- PerkinElmer, which announced that none of the more than 30 mutations associated with the omicron variant impact its PCR-based diagnostic kits; omicron impacts the S gene of SARS-CoV-2, which the PerkinElmer assays don't target for detection; and
- Becton Dickinson, which expressed confidence in the capabilities of both its PCR and rapid antigen tests to detect omicron.

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Takeaway

The US Food and Drug Administration (FDA) has been continually warning labs and healthcare providers to consider the potential impact of viral mutations on COVID-19 test performance. This fall, the agency issued new rules requiring producers of molecular, serology and antigen SARS-CoV-2 tests that have received Emergency Use Authorization (EUA) to take additional steps to account for viral variants, including:

1. **Updated Labeling Requirements:** Test makers must revise their authorized labeling and submit the updated labeling to FDA as a supplement to the EUA within three months.
2. **Performance Evaluation Requirements:** FDA also required test makers to evaluate the impact of SARS-CoV-2 viral mutations on test performance. Evaluation for multianalyte tests must address the impact of SARS-CoV-2 viral mutations and all other target analytes. Evaluations must be performed on an ongoing basis and include any additional data analysis that the agency requests in response to performance concerns.
3. **Additional Labeling Update Requirements:** If requested by FDA, test makers must update their labeling within seven calendar days to include any additional labeling risk mitigations that the agency identifies with regard to the impact of viral mutations on test performance.